

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK**

IN RE SYNERGY PHARMACEUTICALS,  
INC. SECURITIES LITIGATION

This Document Relates To: All Actions

Master File No: 18-cv-00873-AMD-VMS

**SECOND CONSOLIDATED AMENDED  
SECURITIES CLASS ACTION  
COMPLAINT**

**JURY TRIAL DEMANDED**

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## TABLE OF DEFINED TERMS AND ABBREVIATIONS

Term	Definition
<b>2016 Annual Report</b>	Synergy's Annual Report (on Form 10-K) filed with the SEC on March 1, 2017
<b>2Q 2017 Presentation</b>	Synergy's slideshow presentation on August 9, 2017
<b>3Q 2017 Presentation</b>	Synergy's slideshow presentation on November 9, 2017
<b>Amitiza</b>	Amitiza® a/k/a lubiprostone
<b>Bankruptcy Action</b>	<i>In re: Synergy Pharmaceuticals Inc., et al.</i> , No. 1:18-bk-14010 (Bankr. S.D.N.Y. Dec. 12, 2018)
<b>Cash Condition Precedent</b>	The undisclosed terms of the CRG Loan requiring the Company to have \$128 million in cash or cash equivalents as of January 31, 2018 to obtain the second \$100 million tranche of the Loan
<b>CCO</b>	Chief Commercial Officer
<b>CEO</b>	Chief Executive Officer
<b>CFO</b>	Chief Financial Officer
<b>CIC</b>	Chronic Idiopathic Constipation
<b>Class</b>	Subject to certain exclusions, all persons and entities who purchased Synergy securities during the Class Period and were damaged thereby
<b>Class Period</b>	November 10, 2016 through November 13, 2017, both dates inclusive
<b>Company</b>	Synergy Pharmaceuticals, Inc.
<b>CRG Loan</b>	A \$300 million debt financing structured as senior secured loans from CRG LP
<b>CSO</b>	Chief Strategy Officer
<b>Exchange Act</b>	Securities Exchange Act of 1934
<b>FOIA</b>	Freedom of Information Act, 5 U.S.C. § 552, <i>et seq.</i>
<b>GC-C</b>	guanylate cyclase-C
<b>Linzess</b>	Linzess® a/k/a linaclotide
<b>Loan</b>	CRG Loan, which was a \$300 million debt financing structured as senior secured loans from CRG LP
<b>NDA</b>	New Drug Application
<b>PBM</b>	Pharmaceutical benefits manager
<b>Trulance</b>	TRULANCE® a/k/a plecanatide

**TABLE OF PERSONS AND ENTITIES**

<b>Name</b>	<b>Description</b>
<b>Allergan</b>	Allergan, Inc., a multinational pharmaceutical company focused on developing, manufacturing, and commercializing branded pharmaceutical, device, biologic, surgical, and regenerative medicine products
<b>BTIG</b>	An analyst firm which produced, <i>inter alia</i> , research reports covering Synergy
<b>CRG LP</b>	A private equity firm which entered into the \$300 million CRG Loan agreement with Synergy on or around September 1, 2017
<b>Defendants</b>	Collectively refers to defendants Jacob, Garcia, Gemignani, and Hamilton
<b>Express Scripts</b>	Express Scripts Holding Company, the largest independent pharmacy benefits manager in the United States
<b>FDA</b>	United States Food and Drug Administration
<b>Garcia</b>	Defendant Marino Garcia, Synergy's CSO and Executive Vice President during the Class Period
<b>Gemignani</b>	Defendant Gary G. Gemignani, Synergy's CFO and Executive Vice President since April 17, 2017
<b>Hamilton</b>	Defendant Troy Hamilton, Synergy's CCO during the Class Period
<b>Health Monitor</b>	Health Monitor Network is a company hired by pharmaceutical companies to publish, <i>inter alia</i> , condition-specific guides which Health Monitor distributes to doctors' offices nationwide
<b>Ironwood</b>	Ironwood Pharmaceuticals, Inc., a commercial biotechnology company
<b>Jacob</b>	Defendant Gary S. Jacob, Synergy's CEO, President, and director during the Class Period
<b>Jaeger</b>	Synergy's Vice President of Regulatory Affairs & Clinical Quality Assurance, Evelyn Jaeger
<b>Lead Plaintiffs</b>	Robert Tilton, Cross Country Media and Sourcing, Inc., Joseph Badolato, Michael Margulis, and Joseph Buck
<b>NAD</b>	National Advertising Division of the Better Business Bureau
<b>Pfizer</b>	Pfizer Inc., a research-based, global biopharmaceutical company

**TABLE OF PERSONS AND ENTITIES**

Name	Description
<b>PTC</b>	Express Scripts' National Pharmacy & Therapeutics Committee, which is comprised of independent physicians, and recommends whether a medicine should be included in Express Scripts' formulary
<b>QuintilesIMS</b>	A third-party healthcare information company which provides its clients with comprehensive sales, prescription, and promotional data
<b>Regence</b>	Regence Blue Cross Blue Shield, a health insurance provider
<b>Seeking Alpha</b>	SeekingAlpha.com, a financial news website
<b>Synergy</b>	Synergy Pharmaceuticals, Inc.
<b>TAC</b>	Express Scripts' Therapeutic Assessment Committee, which consists of Express Scripts' clinical pharmacists and physicians who review specific medications following FDA approval using medical literature and published clinical trial data
<b>Takeda</b>	Takeda Pharmaceuticals, Inc.
<b>SEC</b>	United States Securities and Exchange Commission
<b>VAC</b>	Express Scripts' Value Assessment Committee VAC consisting of Express Scripts' employees from formulary management, product management, finance and clinical account management, which makes recommendations regarding the value of the drugs to the PTC considering factors such as cost

**GLOSSARY**

<b>Term</b>	<b>Definition</b>
<b>Active Control</b>	When a known, effective treatment (as opposed to a placebo) is compared to an experimental treatment; <i>i.e.</i> , every person in an active control clinical trial is given a treatment that works (or potentially works) instead of some participants receiving a placebo.
<b>Agonist</b>	A chemical substance capable of combining with a specific receptor on a cell and initiating the same reaction or activity typically produced by the binding organically produced substance.
<b>Bristol Stool Scale</b>	A medical chart which categorizes stools based on their shape and consistency, attached hereto as Exhibit A. The scale is used to measure the consistency of stools, and allows patients to talk with their doctors about their stools.
<b>Chronic Idiopathic Constipation (CIC)</b>	Persistent difficult-to-pass or infrequent bowel movements with no identifiable cause.
<b>Diarrhea</b>	A loose and watery stool.
<b>Form 2253</b>	A form required to be submitted to the FDA at the time of initial publication of an advertisement or promotional material for a prescription drug product.
<b>Formulary</b>	A continually updated list of prescription drugs approved for reimbursement by the PBM's payer client ( <i>e.g.</i> , insurers).
<b>Guanylate cyclase-C (GC-C)</b>	A transmembrane receptor that plays an important role in intestinal fluid regulation.
<b>Linzess® a/k/a Linaclotide</b>	The market-leading CIC prescription drug treatment, which is co-marketed by Allergan and Ironwood.
<b>"Me-too" Drug</b>	A drug which is very similar to existing drugs in the same category, and often has only slight differences in the way its chemistry is designed and in how it works.
<b>Microgram</b>	A measuring unit; there are 1 million micrograms in a single gram.
<b>New Drug Application (NDA)</b>	The vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.
<b>Pharmaceutical Benefits Manager (PBM)</b>	Middlemen who process prescription medication claims (for a small fee per claim) for insurance companies and plan sponsors.

**GLOSSARY**

Term	Definition
<b>Phase 3 Clinical Trial/Study</b>	Clinical trials that are conducted in a broader number of patients than a Phase 2 trial to further demonstrate whether the drug offers a treatment benefit and whether the drug is safe.
<b>Stool Consistency</b>	The shape of a stool, as measured by the Bristol Stool Scale.
<b>Trulance® a/k/a Plecanatide</b>	Synergy's primary asset and only commercialized drug product. It is a prescription medicine used for the treatment of CIC in adult patients.
<b>Uroguanylin</b>	A naturally occurring hormone in the human body which increases fluid secretion in the gut by activating GC-C.

**CHRONOLOGY**

<b>Date</b>	<b>Event</b>
<b>Nov. 9, 2016</b>	Post-market close, Synergy, Jacob, and Hamilton make false/misleading statements regarding Trulance's purported superiority with respect to the diarrhea side-effect. ¶¶48-49.
<b>Nov. 10, 2016</b>	Class Period begins.  Synergy privately exchanges 12,911,914 shares of the stock for \$35 million in 7.50% Convertible Senior Notes due 2019. ¶137.
<b>Jan. 19, 2017</b>	FDA approves Trulance for use in adult CIC patients. ¶26.
<b>Feb. 6, 2017</b>	Synergy closes a public offering of 20,325,204 shares at \$6.15 per share, raising approximately \$125 million. ¶137.
<b>Feb. 17, 2017</b>	Synergy disseminates Guide To CIC and makes false/misleading statements regarding Trulance's purported diarrhea side-effect profile within. ¶¶51-55.
<b>Mar. 2017</b>	Synergy begins selling Trulance. ¶29.
<b>Mar. 10, 2017</b>	Synergy and Jacob make false/misleading statements regarding Trulance's purported diarrhea side-effect profile on the Company's website. ¶¶56-60.
<b>Mar. 21, 2017</b>	Synergy and Garcia make false/misleading statements regarding Trulance's purported diarrhea side-effect profile at investor conference. ¶¶61-62.
<b>May 3, 2017</b>	Synergy and Jacob make false/misleading statements regarding Trulance's purported diarrhea side-effect profile at investor conference. ¶¶63-64.
<b>July 31, 2017</b>	Mid-day, Express Scripts excludes Trulance from its 2018 National Preferred Formulary. ¶70.  On this news, Synergy's share price falls \$0.18 per share, or approximately 4.4% from the previous trading day's closing price of \$4.06, to close at \$3.88. ¶71.
<b>Aug. 9, 2017</b>	Post-market close, Synergy discloses slowdown in weekly Trulance prescription growth rate, and cash burn of \$73.6 million compared to net sales of only \$2.3 million. ¶¶72, 74.
<b>Aug. 10, 2017</b>	Synergy's share price falls \$0.46 per share, or approximately 13.03% from the previous trading day's closing price of \$3.53, to close at \$3.07. ¶75.
<b>Sept. 1, 2017</b>	Allergan, marketer of Linzess, writes to the NAD seeking resolution regarding Synergy's false/misleading touting of Trulance's superiority. ¶119.
<b>Sept. 5, 2017</b>	Synergy announces the \$300 million structured CRG Loan, and Synergy, Gemignani, and Jacob make false/misleading statements touting the loan as non-dilutive. ¶¶89-92.
<b>Sept. 7, 2017</b>	Synergy, Jacob, Gemignani, and Hamilton make false/misleading statements about CRG Loan during investor conference call. ¶¶95-96.
<b>Nov. 9, 2017</b>	During a call scheduled to begin at 4:30 p.m., Gemignani/Synergy continue to make false/misleading statements regarding the CRG Loan. ¶¶100-01.

**CHRONOLOGY**

Date	Event
	<p>Synergy also discloses the third quarter slowdown in Trulance’s prescription growth in its slideshow presentation. ¶102.</p> <p>Synergy files with the SEC its Quarterly Report on Form 10-Q for the third quarter of 2017. ¶99.</p>
<b>Nov. 10, 2017</b>	Synergy’s share price falls \$0.25 per share, or approximately 8.42% from the previous trading day’s closing price of \$2.97, to close at \$2.72. ¶103.
<b>Nov. 13, 2017</b>	<p>Pre-market open, Synergy announces a \$56 million public offering of common shares. ¶104.</p> <p>Synergy’s share price falls \$0.28 per share, or approximately 10.3% from the previous trading day’s closing price of \$2.72, to close at \$2.44. ¶105.</p> <p>Class Period ends.</p>
<b>Nov. 14, 2017</b>	<p>Pre-market open, BTIG lowers its price target for Synergy shares, citing “surprise” public offering. ¶106.</p> <p>Seeking Alpha publishes article describing Synergy’s/Gemignani’s November 9, 2017 comments on the Loan as “obfuscation in hindsight, bordering on deliberate misdirection.” ¶107.</p> <p>Synergy shares close at \$2.03, a one-day decline of approximately \$0.41 per share or 16.8%. ¶108.</p> <p>Synergy files final prospectus on Form 424B5 for the \$56 million public offering of common shares. ¶109.</p>
<b>Dec. 19, 2017</b>	Synergy files a Current Report on Form 8-K announcing the resignation of Jacob and that the Company appointed Hamilton CEO on December 13, 2017. ¶147.
<b>Dec. 12, 2018</b>	Synergy files for bankruptcy. ¶¶14, 111.

**TABLE OF EXHIBITS**

<b>Exhibit #</b>	<b>Description</b>
<b>Exhibit A</b>	Bristol Stool Scale Chart from WebMD.com, <i>What Kind of Poop Do I Have?</i> , <a href="https://www.webmd.com/digestive-disorders/poop-chart-bristol-stool-scale">https://www.webmd.com/digestive-disorders/poop-chart-bristol-stool-scale</a> (Oct. 29, 2017)
<b>Exhibit B</b>	Health Monitor Network's Guide To CIC
<b>Exhibit C</b>	Synergy, Apple Inc. App Store, <i>Meet The Poop Troop</i> (screenshotted on June 4, 2018)
<b>Exhibit D</b>	Health Monitor proof of claim
<b>Exhibit E</b>	FDA Form 2253 for March 10, 2017 advertisement on Trulance's Patient Launch Website and corresponding advertisement
<b>Exhibit F</b>	FDA Form 2253 for March 10, 2017 advertisement on Trulance's Health Care Provider Launch Website and corresponding advertisement
<b>Exhibit G</b>	NAD's Sept. 6, 2017 Letter To Jacob regarding "Advertising for Trulance™"
<b>Exhibit H</b>	FDA Form 2253 for February 17, 2017 advertisement in Health Monitor Guide To CIC

The allegations in this Consolidated Amended Securities Class Action Complaint (“Complaint”)<sup>1</sup> are based on the personal knowledge of Plaintiffs Robert Tilton, Cross Country Media and Sourcing, Inc., Joseph Badolato, Michael Margulis, and Joseph Buck (collectively, “Lead Plaintiffs”), as to Lead Plaintiffs’ own acts, and are based upon information and belief as to all other matters alleged herein. Lead Plaintiffs’ information and belief is based upon the substantial investigation by Lead Plaintiffs’ counsel into the facts and circumstances alleged herein, including the following: (i) a review and analysis of public filings referenced herein made by Synergy Pharmaceuticals, Inc. (“Synergy” or the “Company”) with the United States Securities and Exchange Commission (“SEC”); (ii) a review and analysis of press releases, analyst reports, public statements, news articles, and other publications referenced herein disseminated by or concerning Synergy and the Defendants named herein; (iii) a review and analysis of Company conference calls, press conferences, and related statements and other materials referenced herein; (iv) a review and analysis of those documents produced to Lead Plaintiffs’ counsel through a Freedom of Information Act (“FOIA”) litigation with the United States Food and Drug Administration (“FDA”) referenced herein; (v) pleadings and other filings in Synergy’s bankruptcy action referenced herein; and (vi) review and analysis of those other documents referenced herein. Many additional facts supporting the allegations are known only to the Defendants and/or are within their exclusive custody or control. Lead Plaintiffs believe that additional evidentiary support for the allegations will emerge after a reasonable opportunity to conduct discovery.

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<sup>1</sup> All internal citations and quotations are omitted and all emphases are added unless otherwise noted.

## I. NATURE AND SUMMARY OF THE ACTION

1. Subject to certain exclusions, this is a federal securities class action brought on behalf of a class consisting of all persons or entities who purchased publicly traded Synergy securities at artificially inflated prices between November 10, 2016 and November 13, 2017, inclusive (the “Class Period”), and were damaged thereby, which seeks remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and SEC Rule 10b-5 promulgated thereunder.

2. Prior to its bankruptcy, Synergy was a pharmaceutical company with only one commercial product, plecanatide, a prescription medication approved under the trademark name TRULANCE® (“Trulance”) for the treatment of adults with chronic idiopathic constipation (“CIC”). CIC has no identifiable cause and is characterized by persistent difficult-to-pass or infrequent bowel movements.

3. Trulance competes with two other drugs approved by the FDA for the treatment of CIC in adults: (1) Linzess® a/k/a linaclotide (“Linzess”), which is co-marketed by Allergan, Inc. (“Allergan”) and Ironwood Pharmaceuticals, Inc. (“Ironwood”); and (2) Amitiza® a/k/a lubiprostone (“Amitiza”), which is marketed by Takeda Pharmaceuticals, Inc. (“Takeda”). During the Class Period, Linzess was the market-leading CIC prescription drug.

4. Unfortunately, CIC prescription medications often work *too well* when treating CIC, with many patients on these medications experiencing diarrhea. Due to the unpleasant diarrhea side-effect, some patients discontinue their CIC treatments. Thus, the commercial success of CIC treatments is dictated to an important degree by whether patients taking the drug experience diarrhea.

5. During the Class Period, Defendants and Synergy knowingly and/or recklessly made two related categories of false and/or misleading statements about Trulance's side-effect profile and the Company's financing to launch Trulance.

6. First, Defendants and Synergy touted that Trulance has a superior side-effect profile to its competitors, particularly as it relates to a supposedly lower incidence of diarrhea. For example, Defendants claimed that Trulance could help patients avoid the "*extremes*" of diarrhea that patients taking other medications could not avoid. In fact, Defendants had no basis to compare Trulance to its competitors because, as required by the FDA before making such comparisons, no adequate and well-controlled head-to-head study had been conducted comparing Trulance to Linzess or Amitiza. Additionally, the incidence of diarrhea in Trulance's and Linzess' phase 3 trials cannot be compared because they were measured differently. That is, Linzess' phase 3 trials recorded all diarrhea events, whereas Trulance's phase 3 trials recorded diarrhea only if the patient found it "bothersome." Thus, the former methodology was objective whereas the latter methodology was subjective. By touting Trulance as superior with respect to the diarrhea side-effect, when they had no evidence for doing so, Defendants misled investors into believing that Trulance's side-effect profile was superior to its competitors' profile and, correspondingly, Trulance's sales potential was greater than that of its competitors.

7. The risks stemming from Defendants' misrepresentations regarding Trulance's purported side effect profile materialized over time as the market digested new information reflecting Trulance's weakening sales. On November 9, 2017, after market close, Synergy revealed that the pace of Trulance prescriptions grew only 4.4% in the third quarter and that September 2017 was the fourth consecutive month in which the number of Trulance prescriptions written by each individual Trulance prescriber had decreased.

8. Second, on September 5, 2017, Defendants misrepresented that a \$300 million loan the Company had secured from private equity firm CRG LP (the “CRG Loan” or the “Loan”) would fund Synergy until 2019 *without diluting current shareholders’ holdings*, while simultaneously concealing that the terms of the CRG Loan materially increased the likelihood that a dilutive offering would be necessary. The Loan provided Synergy immediate funding of \$100 million, with the remainder of the funding to be obtained in tranches of an additional \$100 million on or before February 28, 2018, and two additional tranches of \$50 million each on or before March 29, 2019. The CRG Loan’s terms, however, required the Company to have \$128 million in cash or cash equivalents as of January 31, 2018 to obtain the second tranche of \$100 million in funding (the “Cash Condition Precedent”). Given the Company’s negative cash flow—Synergy spent almost \$74 million to make a paltry \$2.3 million in Trulance revenue in the quarter preceding the Loan announcement—Synergy needed to dilute investors via a public offering in order to meet the Cash Condition Precedent and access the second tranche of funding. Yet Defendants omitted this material term of the Loan from its disclosures, misleading investors by stating that the Loan was non-dilutive, its funds were available to Synergy “if and when” needed, and that the Loan would fund the commercialization of Trulance through 2019. As a result of Defendants’ fraud, investors saw the CRG Loan as a boon given their concerns that the Company’s depletion of its available cash to fund Trulance’s launch would mean further dilution by additional public and/or private offerings.

9. Despite Defendants’ various statements assuring the market that the CRG Loan was non-dilutive and available to the Company when and if needed, pre-market open on November 13, 2017, Synergy announced a public offering of approximately \$56 million in shares, diluting shareholders’ interests. Among the purposes of this offering was to garner

enough cash to meet the Cash Condition Precedent on the CRG Loan, the existence of which had not been previously disclosed, and to help fund the commercialization of Trulance despite Defendants' previous representations that the CRG Loan provided sufficient funding through 2019.

10. Synergy's share price plummeted following the startling revelation, falling \$0.28 per share, or approximately 10.3% from the previous trading day's closing price of \$2.72, to close at \$2.44 per share on November 13, 2017.

11. Then, pre-market open on November 14, 2017, research analyst firm BTIG lowered the price target for Synergy shares to \$7 from \$11, citing its "surprise" regarding Synergy's new equity offering in light of the Company's prior inconsistent statements regarding the CRG Loan. Also that day, an article on Seeking Alpha, a financial news website, denounced Defendant Gary G. Gemignani's ("Gemignani") statements to analysts regarding Synergy's access to capital under the CRG Loan "when we need it" to be "obfuscation, bordering on deliberate misdirection."

12. On this news, Synergy's share price fell another \$0.41 per share, or approximately 16.8% from the previous trading day's closing price of \$2.44, to close at \$2.03 on November 14, 2017.

13. Based on their purchases of Synergy securities during the Class Period at market prices, Lead Plaintiffs and the Class are presumed to have relied on Defendants' false and misleading statements and omissions. As the true facts and risks were revealed, Lead Plaintiffs and the Class suffered significant damages as a direct and proximate result of Defendants' fraud.

14. While the CRG Loan bought Synergy some extra time, about a year later on December 12, 2018, Synergy filed for bankruptcy.

## **II. JURISDICTION AND VENUE**

15. This action arises under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

16. This Court has jurisdiction over this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331.

17. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, as certain of the acts and conduct complained of herein, including the dissemination and/or omission of materially false and/or misleading information to the investing public, occurred in this District.

18. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, the Internet, and the facilities of the national securities markets.

## **III. THE PARTIES**

### **A. Lead Plaintiffs**

19. Lead Plaintiffs purchased Synergy securities at artificially inflated prices during the Class Period and were damaged thereby when the truth was revealed, as set forth in the certifications submitted to the Court by Robert Tilton, Cross Country Media and Sourcing, Inc., Joseph Badolato, Joseph Buck, and Michael Margulis. ECF No. 10-2 (Tilton's and Cross Country Media and Sourcing, Inc.'s certifications); ECF No. 21-2 (Badolato's and Buck's certifications); ECF No. 53-1 (Margulis' amended certification).

**B. Defendants**

20. Defendant Gary S. Jacob (“Jacob”) was at all relevant times Synergy’s founder, Chief Executive Officer (“CEO”), President, and Chairman of the Board of Directors (“Chairman”) until the Company announced on December 13, 2017 that Jacob resigned his CEO position.

21. Defendant Gemignani was at all relevant times Synergy’s Executive Vice President and Chief Financial Officer (“CFO”) since April 17, 2017.

22. Defendant Marino Garcia (“Garcia”) was at all relevant times Synergy’s Executive Vice President and Chief Strategy Officer (“CSO”). Garcia was terminated from Synergy on September 17, 2018.

23. Defendant Troy Hamilton (“Hamilton”) was at all relevant times Synergy’s Chief Commercial Officer (“CCO”). From December 2017 until the Company was dissolved in bankruptcy, Hamilton has served as the Company’s CEO.

24. Defendants Jacob, Gemignani, Garcia, and Hamilton are collectively referred to herein as the “Defendants.”

**C. Relevant Non-Party**

25. During the Class Period, non-defendant Synergy was a Delaware corporation with its principal executive offices located at 420 Lexington Avenue, Suite 2012, New York, New York 10170. Synergy’s stock traded on the NASDAQ, an efficient market, under the ticker symbol “SGYP.” Synergy was previously named as a defendant in Lead Plaintiffs’ Consolidated Amended Complaint, ECF No. 53, but is not named herein as a defendant as a consequence of its bankruptcy.

#### IV. SUBSTANTIVE ALLEGATIONS

##### A. The Company

26. During the Class Period and prior to its bankruptcy, Synergy was a pharmaceutical company focused on gastrointestinal therapies. Synergy, Form 10-K, filed with the SEC on Mar. 1, 2017, at 3 (“2016 Annual Report”). Synergy’s first and only commercial product, plecanatide, is a prescription medication approved under the trademark name Trulance™ for the treatment of adults with CIC. *Id.* The FDA approved Trulance’s New Drug Application<sup>2</sup> (“NDA”) for CIC on January 19, 2017. *Id.*

##### B. Chronic Idiopathic Constipation (CIC)

27. People with chronic idiopathic constipation have persistent symptoms of difficult-to-pass and infrequent bowel movements. *Id.* at 4. In addition to physical symptoms including abdominal bloating and discomfort, CIC can adversely affect an individual’s quality of life, including increasing stress levels and anxiety. *Id.* Constipation and diarrhea are measured by the Bristol Stool Scale chart, which is attached as Exhibit A.

##### C. FDA-Approved CIC Prescription Treatments

28. During the Class Period, Trulance competed with two other prescription medications for the treatment of CIC: Linzess and Amitiza. 2016 Annual Report at 17. The value of the CIC prescription market is approximately \$1.9 billion and growing. *See* Oct. 3,

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<sup>2</sup> A New Drug Application is “the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.” FDA, *New Drug Application (NDA), Introduction*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>.

2017 Research and Markets Press Release, *Global Chronic Idiopathic Constipation (CIC) Drugs Market, 2025: Emerging APAC Market & High Unmet Needs*.<sup>3</sup>

# **1. Trulance® (Plecanatide)**

29. Synergy's Trulance is approved for treatment of CIC in adults.<sup>4</sup> Trulance is a guanylate cyclase-C<sup>5</sup> ("GC-C") agonist which is "structurally related to human uroguanylin[.]" See Jan. 19, 2017 Synergy Press Release, *Synergy Pharmaceuticals' Trulance™ (Plecanatide) Receives U.S. FDA Approval for the Treatment of Adults with Chronic Idiopathic Constipation*. Trulance "works locally in the upper GI [gastrointestinal] tract to stimulate secretion of intestinal fluid and support regular bowel function." Jan. 19, 2017 FDA Press Release, *FDA approves Trulance for Chronic Idiopathic Constipation*. Synergy began distributing Trulance in March 2017. See May 10, 2017 Synergy Press Release, *Synergy Pharmaceuticals Reports First Quarter 2017 Financial Results and Business Update*.<sup>6</sup> Trulance costs approximately \$414 for a 30 once-a-day supply of tablets. See Drugs.com, *Trulance Prices, Coupons and Patient Assistance Programs*.<sup>7</sup>

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<sup>3</sup> <https://www.prnewswire.com/news-releases/global-chronic-idiopathic-constipation-cic-drugs-market-2025-emerging-apac-market--high-unmet-needs-300529917.html>.

<sup>4</sup> <https://www.trulance.com/>.

<sup>5</sup> GC-C is a transmembrane receptor which is important in regulating intestinal fluids. See Gerhard Hannig, *et al.*, *Guanylate cyclase-C/cGMP: an emerging pathway in the regulation of visceral pain*, Mol. Neurosci., <https://www.frontiersin.org/articles/10.3389/fnmol.2014.00031/full>.

<sup>6</sup> <https://ir.synergypharma.com/press-releases/detail/1848/synergy-pharmaceuticals-reports-first-quarter-2017>.

<sup>7</sup> <https://www.drugs.com/price-guide/trulance>.

30. Trulance's most common side effect is diarrhea, which can sometimes be severe. In Trulance's phase 3 trials,<sup>8</sup> diarrhea occurred in 5% of patients treated with Trulance versus 1% of patients who were given a placebo. 2016 Annual Report at 5. ***However, Trulance's Phase 3 Trials recorded diarrhea only if it was reported by the patient as "bothersome."*** See Mark G. Currie, PhD, *et al.*, The American Journal of Gastroenterology, *Response to Miner et al.*<sup>9</sup>

## 2. Linzess® (Linaclotide)

31. Allergan, Inc. ("Allergan") and Ironwood Pharmaceuticals, Inc. ("Ironwood") co-market Linzess, which was first approved for CIC in August 2012 at a 145 microgram (mcg) dose. Ironwood, Annual Report on Form 10-K, at 6-7 (filed with the SEC on Feb. 22, 2018). In January 2017, the 72 mcg dose was approved for treatment of CIC. *Id.* at 6. Linzess is the leading pharmaceutical drug used to treat CIC. See Sept. 7, 2017 Synergy Presentation, *Business Update Call*, at 21. Linzess's 145 mcg and 72 mcg cost \$412 for a supply of 30 once-a-day capsules. See Drugs.com, *Linzess Prices, Coupons & Patient Assistance Programs*.<sup>10</sup>

32. Like Trulance, Linzess is also a GC-C agonist that is "structurally related to human uroguanylin and guanylin" and increases intestinal fluid secretion. Allergan & Ironwood, *LINZESS works differently from laxatives*.<sup>11</sup> In Linzess's Phase 3 trials, diarrhea was also Linzess's most common side-effect. *Id.* ***However, in contrast to Trulance, Linzess's trials recorded all diarrhea events, whether or not the patient reported them as "bothersome."*** *Id.*;

<sup>8</sup> Phase 3 trials provide the critical documentation of effectiveness and important additional safety data required for licensing. See FDA, *Step 3: Clinical Research*, <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>.

<sup>9</sup> <https://www.nature.com/articles/ajg2017362>.

<sup>10</sup> <https://www.drugs.com/price-guide/linzess>.

<sup>11</sup> <https://www.linzesshcp.com/MOA>.

See Mark G. Currie, PhD, *et al.*, *The American Journal of Gastroenterology*, *Response to Miner et al.*

### 3. Amitiza® (Lubiprostone)

33. Amitiza was first approved by the FDA on January 31, 2006. Amitiza is indicated both for CIC and IBS-C, in dosages of 24 mcg twice daily and 8 mcg twice daily, respectively. Takeda Pharmaceuticals, Inc., *Amitiza (Dosing)*.<sup>12</sup> Amitiza costs approximately \$395 for a supply of 60 twice-a-day capsules. See *Drugs.com, Amitiza Prices, Coupons and Patient Assistance Programs*.<sup>13</sup> In clinical trials of Amitiza in patients with CIC, approximately 12% of patients who received Amitiza 24 mcg twice daily experienced diarrhea versus 1% of patients who received a placebo. Takeda Pharmaceuticals, Inc., *Amitiza (Dosing)*.

#### D. Diarrhea Is A Major Concern For Patients Using CIC Prescription Treatments

34. During the Class Period, Synergy conducted a survey dubbed the “BURDEN-CIC Study,” which asked patients and doctors about their experience with CIC medications. See May 7, 2017 Synergy Press Release, *Synergy Presents New Insights at Digestive Disease Week (DDW) Examining Patients and Physician Perceptions and Experiences with Chronic Idiopathic Constipation (CIC)*.<sup>14</sup> The BURDEN-CIC Study reported that both “HCPs [health care providers] and patients said diarrhea is an unacceptable side effect with current CIC treatments,” with 34% of health care providers and 54% of patients who discontinued treatment citing diarrhea as a “key challenge with current prescription treatments.” *Id.*

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<sup>12</sup> <https://www.amitizahcp.com/dosing>.

<sup>13</sup> <https://www.drugs.com/price-guide/amitiza>.

<sup>14</sup> BURDEN-CIC is an acronym for “Better Understanding and Recognition of the Disconnects, Experiences and Needs of Patients with Chronic Idiopathic Constipation.” *Id.*

35. Synergy’s management also highlighted the problem of CIC medications’ diarrhea side-effect in conference calls with investors. For example, in a conference call with investors on August 16, 2012, Defendant Jacob knocked competitor Linzess, stating it was an “enterotoxin” of E. coli, which “produces a flagrant diarrhea.” Synergy at Canaccord Genuity’s Global Growth Conference on Aug. 16, 2012, Fair Disclosure Wire Transcript at 4. Furthermore, during the Class Period, Synergy published a guide claiming that “many people who tried prescription options to treat their constipation complained that they led to diarrhea.” *See* Ex. B at 13.<sup>15</sup>

36. In fact, Synergy even developed a set of animated emojis,<sup>16</sup> dubbed the “Poop Troop,” with each character representing a type of bowel movement, *including diarrhea*, so that patients can “communicate their physical symptoms” to their doctors. *See* Apr. 6, 2017 Synergy Press Release, *Synergy Pharmaceuticals Launches The Poop Troop, The First Emoji Keyboard Designed To Support Dialogue Around Chronic Idiopathic Constipation*; Ex. C (showing emoji characters representing diarrhea stools).

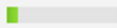
37. A review of comments on Drugs.com for CIC prescriptions also confirms that patients on Linzess and Amitiza sometimes find that these drugs sometimes work *too well*. The following reviews are from patients taking Linzess and experiencing diarrhea:

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<sup>15</sup> Synergy’s Guide To CIC is attached to this Complaint as Exhibit B.

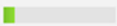
<sup>16</sup> An emoji is “a small digital picture or pictorial symbol that represents a thing, feeling, concept, etc., used in text messages and other electronic communications and usually part of a standardized set[.]” Dictionary.com, *emoji*, <https://www.dictionary.com/browse/emoji?s=t>.

**For Constipation, Chronic** "I have IBS-c (irritable bowel syndrome with constipation) and I found no relief from anything. I went to the doctor and she gave me linzess, I was so excited and had high hopes. I took my first dose this morning at 8:30am and ate at 9:15am not even 20 minutes after I had explosive diarrhea and it is now 1:30pm and I've been about 7 times. I work and want a life so this is definitely not for me. My stomach is still rumbling and I feel horrible. I feel worse than I before."

 1.0

Ky (taken for less than 1 month) August 14, 2018

**For Irritable Bowel Syndrome** "This medicine is useless. Still have 2-4 days of diarrhea then 3-5 days of constipation... and on and on. All it did was blow up my belly like hot air balloon."

 1.0

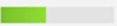
ibs babe June 16, 2018

Drugs.com, *User Reviews for Linzess*,

<https://www.drugs.com/comments/linaclotide/linzess.html>.

38. The following review is from a patient taking Amitiza and experiencing diarrhea:

"55 yr old female, chronic constipation my whole life. I have tried everything, OTC to Linzess which did nothing. I am thin, exercise, high fiber, flax, metamucil, probiotic, and nothing. I go 4-5 days then take 3 ducolax, magnesium citrate and pray. Now that doesn't work. Colonoscopy ruled out anything "serious". Prescribed 24mcg Amitiza. Ate breakfast took the pill and within an hour I was SO SICK. I had explosive diarrhea, felt faint, nauseous, cold chills and sweating. Laying on my bathroom floor going back and forth to the toilet, thought I would throw up too. But I went! I did not take it again because of the side effects. Doc gave me 8mcg. I'm scared to take it. It's awful that I would even think of taking it again just to go to the bathroom"

 4.0

coach17 May 11, 2017

Drugs.com, *User Reviews for Amitiza*, <https://www.drugs.com/comments/lubiprostone/amtiza-for-constipation-chronic.html>.

39. Accordingly, investors, doctors, and patients were looking for a drug which could treat CIC without inducing diarrhea—and the Defendants set out to exploit this unmet need by stating or implying that Trulance was a superior choice to its competitors in this regard even though Synergy had no evidence to say so.

#### **E. The FDA Requires Substantial Evidence In The Form Of Head-To-Head Trials For Superiority Claims**

40. The FDA requires *substantial evidence* in support of any claim that one drug is superior to another. *See* FDA, Guidance For Industry, Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format, at 6 (2006). To meet this evidentiary requirement for comparative claims, the FDA explicitly requires a head-to-head trial:

*For superiority claims, such evidence would include adequate and well-controlled trials designed to establish superiority of one treatment over another. . . . For each type of [comparative] trial, the active control<sup>17</sup> should be used at an appropriate dose and regimen, generally the highest recommended dose, and in an appropriate patient population.*

*Id.*

41. Additionally, “[c]omparative safety claims for drugs in terms of frequency, severity, or character of adverse reaction must be based on data from adequate and well-controlled studies.” FDA, *Guidance for Industry, Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format*, at 9 (2006) (citing 21 CFR § 314.126). In the absence of adequate and well-controlled head-to-head trials, the FDA advises that “[b]ecause clinical trials are conducted under widely varying conditions, *adverse*

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<sup>17</sup> “Active control” “means that a known, effective treatment (as opposed to a placebo) is compared to an experimental treatment. In other words, *every person in an active control clinical trial is given a treatment that works (or potentially works)*, instead of some receiving an inactive sugar pill [placebo].” Statistics How To, *Active Control/Active Comparator: What is an Active Control?*, <http://www.statisticshowto.com/active-control-comparator/> (Mar. 3, 2017).

*reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.”* FDA, *Guidance for Industry, Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format*, 3-4 (2006).

42. The FDA has enforced this head-to-head trial requirement in the face of superiority claims in several instances, including the following:

- On June 19, 2012, the FDA issued a letter chiding Pfizer Inc. (“Pfizer”) for suggesting that Zmax (azithromycin) “demonstrates a superior safety profile when compared to other antibiotics due to the supposed superior tolerability of the drug.”<sup>18</sup> Specifically, Pfizer claimed that “Zmax is different from other drugs, because it’s not released in the stomach . . . [u]nlike many other drugs, you should take Zmax on an empty stomach.” *The FDA found this misleading because it was “not aware of adequate and well-controlled head-to-head studies to support” Pfizer’s safety superiority claim.*
- On February 5, 2013, the FDA issued a letter reprimanding Alcon Research, Ltd. for making superiority claims regarding its eye allergy medication by claiming that “[m]any [eye allergy medicines] only minimize itch, but PATADAY™ . . . eliminates it (zero-itch).”<sup>19</sup> *The*

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<sup>18</sup> <http://wayback.archive-it.org/7993/20161022232827/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM310527.pdf>.

<sup>19</sup> <http://wayback.archive-it.org/7993/20161022232632/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegula>

*FDA found such claims misleading because “claims of superiority must be supported by adequate and well-controlled head-to-head clinical trials comparing appropriate doses and dose regimens of your drug and the comparator drug or drugs.” Id. at 3. The FDA also concluded that a “post-hoc analysis” does not constitute substantial evidence or substantial clinical experience of superiority.*

- On May 7, 2007, the FDA issued a letter warning GlaxoSmithKline plc for making “unsubstantiated superiority claims” regarding Flonase (fluticasone propionate) over its competitor Nasonex.<sup>20</sup> *The FDA found that GlaxoSmithKline lacked “substantial evidence” because the Flonase claims were not based on “adequate, well-designed, head-to-head trials.” Id. at 2.*
- On August 26, 2011, the FDA issued a letter chiding Ortho-McNeil-Janssen Pharmaceuticals, Inc. for claiming that its drug Nuycenta was “similar to tramadol, but with less GI, constipation, nausea, and vomiting.”<sup>21</sup> *The FDA found this statement to be misleading because it*

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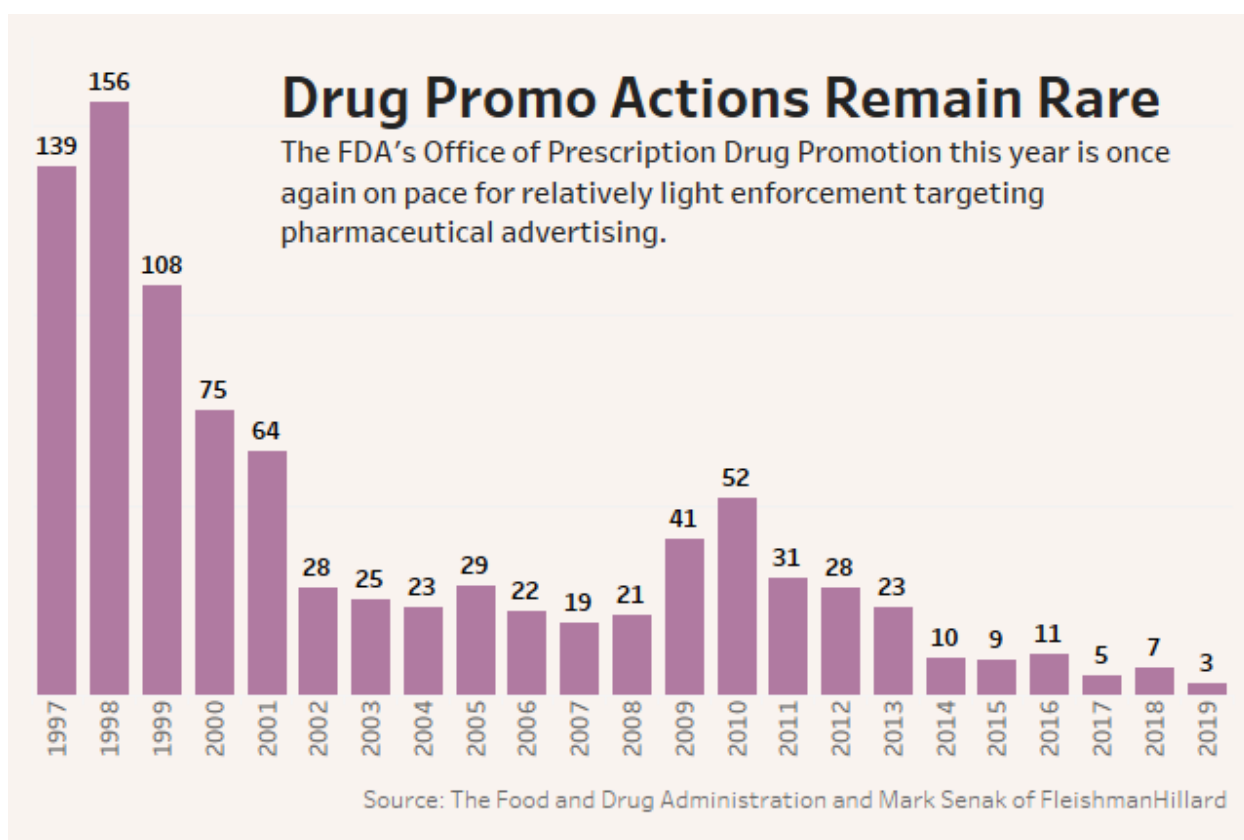
toryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM340334.pdf.

<sup>20</sup> <http://wayback.archive-it.org/7993/20161022234647/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054211.pdf>.

<sup>21</sup> <http://wayback.archive-it.org/7993/20161022233108/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM285974.pdf>.

*was not “aware of any adequate and well-controlled, head-to-head clinical trials comparing the incidence of constipation, nausea, or vomiting for Nucynta versus tramadol.” Id. at 3.*

43. The absence of an FDA enforcement action against a drug company is not evidence that a drug company did not violate the FDA’s rules. Indeed, FDA enforcement of advertisement requirements has substantially declined over the last 6 years, as depicted in the chart below:



Jeff Overly, Law360, *FDA Decries Drugmaker’s Promos On Facebook, ‘The View’*, <https://www.law360.com/articles/1171679> (published June 21, 2019). Thus, the fact that the FDA has not taken action against Synergy does not exculpate Defendants and Synergy with respect to Synergy’s false and/or misleading claims regarding Trulance, *see infra* §I.G.

**F. Defendants And Synergy Possessed No Evidence That Trulance's Diarrhea Side-Effect Profile Was Superior To Other CIC Prescription Treatments**

44. During the Class Period, Defendants and Synergy misrepresented that Trulance was superior to its competitor drugs, Linzess and Amitiza, with respect to causing diarrhea as a side-effect. Specifically, Defendants and Synergy expressly or impliedly stated that Trulance was superior to other prescription CIC treatments because Trulance treated CIC without the “extremes” of diarrhea seen in the use of other medications.

45. Despite the FDA's requirement for substantial evidence in the form of head-to-head trials to support superiority claims, ¶¶40-43, Synergy did not conduct an adequate and well-controlled trial comparing Trulance to Linzess and/or Amitiza, and therefore possessed *no evidence sufficient to support its claims regarding* Trulance's superiority to those drugs with respect to the diarrhea side-effect. To the contrary, Synergy's Phase 3 trials compared Trulance with a placebo, not with any of its competitors or any other drug for that matter. *See* 2016 Annual Report at 5. Therefore, Defendants and Synergy had no basis to tout Trulance's diarrhea side-effect profile as superior to existing CIC therapies, and the omission of that fact renders their statements materially incomplete to the point that they were false and misleading.

46. Additionally, Synergy's Phase 3 Trulance trials recorded diarrhea events differently than Allergan did with respect to Linzess' Phase 3 trials by only recording diarrhea that was deemed “bothersome” by the patient, a patently subjective standard. *See* Mark G. Currie, PhD, *et al.*, The American Journal of Gastroenterology, *Response to Miner et al.*. Thus, any comparison between Trulance and Linzess' diarrhea rates based on non-head-to-head trials would have been improper additionally because the two drugs' trials recorded diarrhea events differently.

47. For example, during the Class Period, Defendants and Synergy claimed that patients using Trulance would not experience the “extremes” of diarrhea that resulted from other medications, and that patients could avoid the “compromise” of diarrhea from those same medications by taking Trulance instead. *See, e.g.*, ¶¶48, 52-53, 56, *infra*. Indeed, Defendants’ and Synergy’s statements led investors—and analysts—to believe that Trulance was superior to Linzess and Amitiza. *See, e.g.*, Mar. 28, 2017 Rodman & Renshaw Analyst Report, *Company Update Healthcare: Trulance™ Supplemental New Drug Application Filed; Reiterate Buy* (“Plecanatide’s safety profile, however, appears **clearly superior**[.]”); *see also* Dec. 9, 2016 Canaccord Genuity Analyst Report, *Company Update: First Phase 3 data positive in IBS-C, much lower diarrhea vs. Linzess*; Mar. 28, 2017 Rodman & Renshaw Analyst Report, *Company Update Healthcare: Trulance™ Supplemental New Drug Application Filed; Reiterate Buy* (Mar. 28, 2017) (“Plecanatide’s safety profile, however, appears **clearly superior**[.]”); June 2, 2017 BTIG Analyst Report, *Synergy Pharmaceuticals, Inc.: Marketing Efforts Behind Trulance Beginning to Take Hold; Weekly RX’s Hit a New High*, at 1 (“We believe a **key source of differentiation with Trulance (plecanatide) is its low incidence of side effects, namely diarrhea**, a ~5% incidence (vs. ~1% with placebo).”). As a result, investors were misled to believe that Trulance had a clear advantage over Linzess—the leading CIC prescription drug—and that Trulance could thus supplant Linzess as the preferred treatment option. *See, e.g.*, June 12, 2017 Rodman & Renshaw Analyst Report, *Trulance Supplemental New Drug Application for Review; Reiterate Buy* (“**We continue to anticipate that Trulance[] should be able to achieve a market-leading position in treatment of both chronic idiopathic constipation (CIC) and IBS-C in the coming years.**”).

**G. Defendants And Synergy Make False And/Or Misleading Statements Touting Trulance's Supposed Superiority With Respect To Causing Diarrhea As A Side-Effect<sup>22</sup>**

48. The Class Period starts on November 10, 2016, the first trading day after Synergy reported its financial results for the third quarter of 2016. In a press release published after the market close on November 9, 2016, titled "Synergy Pharmaceuticals Reports Third Quarter 2016 Financial Results and Business Update" (filed with the SEC as an attachment to a Current Report on Form 8-K signed by Defendant Jacob), Synergy and Defendants Jacob and Hamilton stated in relevant part:

Safety and Tolerability of Plecanatide in Patients with Chronic Idiopathic Constipation: Long-term Evidence from an Open-Label Study

*Data presented from the long-term open-label safety study showed plecanatide was associated with low adverse events and low discontinuation rates in patients with CIC who received plecanatide (3 mg or 6 mg) once-daily for up to 72 weeks.* The most common adverse events were diarrhea (7.1%) and urinary tract infection (2.2%). The remainder of adverse events occurred in less than 2% of patients treated with plecanatide. Adverse events leading to discontinuation occurred in 5.3% of patients treated with plecanatide, with discontinuation due to diarrhea occurring in 3.1% of patients. In addition, this study asked patients about level of treatment satisfaction and desire to continue treatment. The median score for treatment satisfaction was 4.0 (4=quite satisfied) and for continuation of treatment was 4.0 (4=quite likely).

Efficacy and Safety of Plecanatide in the Treatment of Chronic Idiopathic Constipation (CIC): Pooled Results from Two Phase 3 Studies

Pooled results from two previously reported double-blind placebo-controlled phase 3 CIC trials confirmed patients treated with plecanatide showed a significantly greater response rate of durable overall complete spontaneous bowel movements compared to placebo (20.5% in 3 mg and 19.8% in 6mg dose groups compared to 11.5% in placebo;  $p < 0.001$  for both doses). This is the primary endpoint defined by the FDA for regulatory approval in CIC. This integrated analysis also showed consistent safety data with adverse event rates similar across plecanatide-treatment groups and placebo (30.6% in 3 mg and 31.1% in 6 mg dose groups compared to 28.7% in placebo). Diarrhea was the most common

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<sup>22</sup> With respect to statements flagged as false and/or misleading in this Complaint, the statements being challenged as false and/or misleading are those statements that are ***bolded, italicized, underlined, or otherwise highlighted*** for emphasis. All false and/or misleading statements identified in this Complaint were knowingly and/or recklessly made by the identified speakers.

adverse event (4.6% in 3 mg and 5.1% in 6 mg compared to 1.3% in placebo). Discontinuation rates were low across all treatment groups (4.1% in 3.0 mg and 4.5% in 6.0 mg dose groups compared to 2.2% in placebo).

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“We are laser-focused on our key strategic imperatives of product readiness, market and brand readiness and organizational readiness,” said Troy Hamilton, Executive Vice President and Chief Commercial Officer of Synergy Pharmaceuticals Inc. ***“Based on our extensive market research, advisory board meetings and interactions with payers, healthcare providers and patients to-date, we are very encouraged about the positive impact that plecanatide will have in the market place as a differentiated therapeutic option for patients with CIC.*** We are also pleased with the progress our technical operations team has made this year to ensure plecanatide product supply will be ready and available to physicians and patients by our anticipated launch early next year. We strongly believe that we have the right strategy and right team to successfully launch plecanatide and address the unmet needs of a growing GI market.”

49. The statements by Defendants Jacob and Hamilton in ¶48 above were false and/or misleading when made because Trulance was not a differentiated therapeutic option for patients with CIC as:

- a) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;
- b) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and
- c) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance’s Phase 3 trials recorded/defined diarrhea in a different manner than Linzess’ trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea “bothersome,” ¶¶30, 32, 46.

50. On January 19, 2017, the FDA approved Synergy’s NDA for Trulance for the treatment of CIC in adults. *See* 2016 Annual Report at 3. As explained below, Synergy

thereafter ratcheted up its efforts to promote Trulance as a superior drug to Linzess and Amitiza by claiming Trulance had a superior side-effect profile with respect to diarrhea.

51. For example, on or around February 17, 2017, Data Communications, Inc. d/b/a Health Monitor Network (“Health Monitor”) published a “Guide To CIC” paid for by Synergy. *See* Exs. B, D. Health care companies such as Synergy can hire Health Monitor to publish “patient-education” guides for the purpose of “brand[] messag[ing].” *See* Health Monitor, *Print Products*.<sup>23</sup> In fact, Health Monitor touts that its condition-specific guides have a return on investment “averaging 10-to-1” for pharmaceutical company clients, and further touts an “ability to reach 95% of a brand’s key physician office targets,” distributing its magazines to “200,000 healthcare offices around the country[.]” *Id.* In Synergy’s bankruptcy proceedings, Health Monitor filed a proof of claim for \$739,881.50 against Synergy for “goods and services” provided to Synergy, thus establishing that Synergy employed Health Monitor to publish Synergy’s patient-education Guide To CIC. *See* Ex. D (Health Monitor proof of claim).

52. Synergy’s Guide To CIC explicitly stated the following, “Until recently, many people who tried prescription options to treat their constipation complained that they led to diarrhea. ***Now there’s a treatment that treats constipation without causing diarrhea.*** Ask your doctor if this option makes sense for you.” Ex. B at 13. On the next page was an advertisement for Trulance, which stated, “***Does managing your constipation come with compromise?***” *Id.* at 14. The advertisement also depicted seven figures, with the far-left figure representing a stool by someone who is constipated and the far-right figure representing someone suffering from diarrhea. *Id.* ***This image***, with the woman in the center depicting a person on Trulance, was an obvious reference to the seven-stool state categories outlined in the Bristol Stool Scale, which is

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<sup>23</sup> <http://www.healthmonitornetwork.com/print.html>.

a tool that categorizes stool based on its shape and consistency, and was an obvious attempt to imply that Trulance users do not suffer diarrhea as a side-effect as indicated in the last paragraph on the prior page of the Guide To CIC. *See* Ex. A (Bristol Stool Scale chart).

53. When confronted by Allergan (Linzess' co-marketer) about the claims in the Guide To CIC and other Synergy advertisements, Jacob responded in an October 17, 2017 letter by stating, "[W]e stand behind *our advertising and promotional materials and activities*[" and that such materials were part of "*our on-going review*" evidencing that Jacob and Synergy had control over and ultimate authority over the Guide To CIC's contents. ECF No. 39-2 at 18. As well, Jacob, as a director of a Delaware corporation, was under a duty to ensure that Synergy's public disclosures were not false and/or misleading establishing that Jacob had ultimate authority over the Guide To CIC and other advertisements.

54. The statements by Synergy and Jacob in ¶¶52-53 above and highlighted in pages 13-14 of Exhibit B were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) One of the side effects of Trulance—like other CIC medications—is diarrhea, ¶¶30, 32-33;
- b) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;
- c) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and
- d) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance's Phase 3 trials

recorded/defined diarrhea in a different manner than Linzess’ trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea “bothersome,” ¶¶30, 32, 46.

55. Despite Jacob’s ongoing review of promotional materials, at no point during the Class Period did Jacob correct or update the aforementioned false and/or misleading statements listed in ¶¶48, 52-53.

56. On March 10, 2017, Synergy stated on its website promoting Trulance that patients “*shouldn’t have to go to extremes for [their] Chronic Idiopathic Constipation*” and that “*diarrhea isn’t the goal of constipation relief[,] [i]t’s a compromise.*” The statement also depicts seven figures, with the far-left figure representing a stool by someone who is constipated and the far-right figure representing someone suffering from diarrhea. *This image*, with the woman in the center depicting a person on Trulance, was an obvious reference to the seven-stool state categories outlined in the Bristol Stool Scale, which is a tool that categorizes stool based on its shape and consistency, and was an obvious attempt to imply that Trulance users do not suffer diarrhea as a side-effect. See Ex. A (Bristol Stool Scale chart). The patient website image is attached to this Complaint as Exhibit E.<sup>24</sup>

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<sup>24</sup> As explained in ¶142, *infra*, Trulance’s website eventually deleted the claims in ¶¶56, 59. However, Lead Plaintiffs’ counsel, through a litigation involving a FOIA request with the FDA, was able to obtain Form 2253s filed with the FDA and signed by Synergy’s Vice President of Regulatory Affairs & Clinical Quality Assurance, Evelyn Jaeger (“Jaeger”), including two Form 2253s indicating that the advertisements were published on Trulance’s website during the Class Period. See Exs. E, F. Furthermore, Form 2253s list, *inter alia*, the initial publication date of the advertisements and a material ID code which identifies the advertisement. See Exs. E, F. Form 2253’s are required to be submitted to the FDA “at the time of initial publication of the advertisement for a prescription drug product.” See FDA, *FDA Form 2253 Submission*, <https://www.fda.gov/downloads/Drugs/UCM448757.pdf> (May 11, 2015).

57. The statements by Synergy and Jacob in ¶56 above and highlighted in Exhibit E were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;
- b) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and
- c) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance's Phase 3 trials recorded/defined diarrhea in a different manner than Linzess' trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea "bothersome," ¶¶30, 32, 46.

58. Despite Jacob's ongoing review of promotional materials, at no point during the Class Period did Jacob correct or update the aforementioned false and/or misleading statements listed in ¶56.

59. On that same day, March 10, 2017, Synergy stated on its website for healthcare professionals that "***Diarrhea is not efficacy—It's time to address the age-old tradeoff in CIC. Now there's Trulance[.]***" The statement also *depicts the same seven figures* described in ¶56, above. The healthcare professional website image is attached to this Complaint as Exhibit F.

60. The statements by Synergy and Jacob in ¶59 above and highlighted in Exhibit F were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;
- b) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and
- c) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance's Phase 3 trials recorded/defined diarrhea in a different manner than Linzess' trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea "bothersome," ¶¶30, 32, 46.

61. On March 21, 2017, at the Oppenheimer Healthcare Conference, Synergy and Defendant Garcia stated in relevant part:

***So very strong efficacy, clearly this is what patients are looking for. But it's not just about increasing bowel movements. Having unlimited bowel movements is not what patients are really looking for in terms of normal. What they are looking for is, of course, increased bowel movements, but also normal stool consistency, what they don't want is to be cycling constantly between the constipated hard stools, the painful hard stools or the diarrhea, the side effects they might suffer from some of the treatments they've been on in the past.***

***And you can see in this slide with the Bristol Stool Form Scale. Clearly, when a patient is put on three milligrams right from the first week, they go right to the middle of the Bristol Stool Form Scale, to the 4 or what our illustrious Chief Medical Officer, Dr. Patrick Griffin, likes to call the magic sausage, but it's just amazing how right at three milligrams the patients sit right on that line right to the end of the trial. And when they discontinue, obviously, right back down to the harder, more constipated stool consistency.***

***This is really important to the patients. They want to feel normal, and this is the promise of Trulance. And, of course, the question then is, so can you do this with a safety and tolerability profile. That's ideal for these patients that lets them not have to constantly cycle between the extremes. And, as you can see from our label, it's just – we were impressed. There is just one side effect mentioned that's greater than placebo and over 2% in the combined trials and that's diarrhea at 5%. So we are really, really pleased with how the efficacy and the side effect profile worked out for our label.***

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We looked at how could we present this product to the patient and help them with managing the condition and empowering them even further. We were approved -- TRULANCE was approved -- to be sold in two different ways, in bottles or in a blister dose pack, and the market research for the blister dose pack was so overwhelmingly positive that we are actually going to be able to claim and let physicians know that this is what patients prefer. This is a dose pack where patients will be able to see the four weeks laid out for their treatment. They will be able to track how they are taking the drug and we think this is a drug that you are going to be able to take every day. And then there will be to extract tablets that say it's time for your refill, and the feedback was incredibly positive. We think this will provide an even more positive experience for the physician and the patient in terms of making it easier for patients to take their medication. So, this - - we think it's just a winning combination of efficacy, safety, tolerability, ease-of-use, and even in the presentation with this blister pack. So we're very excited and this is now available across the country. So, we've talked a little bit about the market.

We've talked a little bit about the product, now let's talk about the strategy. I am very excited to share this -- and you can go to our website and see more of it, but it is incredibly powerful creative campaign based on a lot of marketing insights from a lot of marketing research, and we are really pleased. This is the kind of campaign marketers dream of because you usually have trouble finding a campaign that works both for healthcare providers as well as patients, that really scores very well and we're off the charts.

This campaign scored off the charts for both groups. So it's been a consistent in terms of the messaging, images and creative campaign aimed at both groups, at the patients and the healthcare providers, pharmacists, physicians, etc. ***And the whole point is that with chronic constipation, the trade-offs that patients have had to make, the extremes they've had to go from constipation or to diarrhea because of some of the medications they may have been on in the past, that they no longer have to make that trade-off. That Trulance provides the promise of being able to make patients feel like they are normal, right smack in the middle between the extremes.***

Synergy at Oppenheimer Healthcare Conference on Mar. 21, 2017, Fair Disclosure Wire

Transcript at 3-4 .

62. The statements by Defendant Garcia in ¶¶61 above were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;

- b) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and
- c) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance's Phase 3 trials recorded/defined diarrhea in a different manner than Linzess' trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea "bothersome," ¶¶30, 32, 46.

63. On May 3, 2017, at the Deutsche Bank Health Care Conference, Synergy and Defendants Jacob and Hamilton stated, in relevant part:

[Troy Hamilton]: The next strategy and activity has to do with what we're doing around activating and supporting the Rx-ready patient. So I mentioned before we have a ton of patients now that are enabled to go in and talk to their doctors. And for the most part, they are patients that have tried OTC agents and are Rx-ready. So we want to also try to activate those patients, but support and leverage to have them exposed to one of our branded or unbranded campaigns. So we have 2 going on. This is more direct-to-patient initiatives. The Trulance campaign is the branded campaign. We have a lot going on here. There is point-of-care promotions, so that would be in-office print or displays. We're focusing on 20,000 offices there. We have web sponsorships in display ads. To date, we've already had over 16 million media impressions. We have search engine marketing, where we had over 55,000 clicks, so that would be someone would do a search, new CIC options, Trulance will pop up, you would click on it. That's essentially a click. And for the trulance.com site, for just the consumer site, we've had close to 65,000 visits. And for the HCP site, it's now approaching 20,000 or 25,000 visits. So that is the branded campaign. We also have the unbranded campaign. This is the disease awareness initiative, confront constipation campaign. We had the hook of the poop troop emojis, which, I'm sure, many of you have seen. It created a lot of buzz and engagement and perhaps it made some folks feel uncomfortable, but that's exactly how the patients feel. We thought it was very important to do whatever we can to try and help that physician-patient dialogue. The great thing is the marketing team worked with patients and physicians to actually develop this campaign. The results have been unbelievable. We've had 28 original media placements or articles in places like The Wall Street Journal and Cosmopolitan magazine. We've had over 300 million media impressions. And this is just in last 4 weeks. And interestingly, we've had almost 50,000 emoji app downloads. Again, we're just getting started. The other great thing is a lot of these patients have gone to the confront constipation website to review information on uroganylin and the Bristol Stool Form Scale and even download information. And it also created a lot of buzz and awareness around Synergy. And the great thing, this is an

extremely cost-efficient way to create buzz when you're developing an app in a website. So a lot of great activities on the patient front.

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[Unidentified Analyst]: What arguments do your representatives use to convince leading health care providers to switch from linaclotide [Linzess] to plecanatide [Trulance]? And conversely, what arguments do Ironwood reps use to keep those leading HCPs prescribing linaclotide? And I have a couple more.

[Gary Jacob]: Thanks for the question. We're not going to obviously, dive into our message platform for competitive reasons, but as we both discussed and as I talked about when – with the one slide that looked at our profile and ingrained in kind of what we get from the label. ***Our discussions are based on pharmacology, the efficacy, the safety/tolerability and the dosing, the balance of that approach. And you probably see that in some of the other materials that we have in our campaign right now. So that's kind of what we're talking to.*** I can't really talk to the competition. I do know obviously they've been out there for long period of time and have had kind of a standard approach. But for us, we're focused on that balance between the pharmacology, the reason I believe, the efficacy, safety/tolerability and the dosing.

Synergy at Deutsche Bank Healthcare Conference on May 3, 2017, Fair Disclosure Wire

Transcript at 6, 7 .

64. The statement by Synergy and Defendant Jacob in ¶¶63 above was false and/or misleading when made because Synergy's marketing campaign was misleading as the following facts were omitted or misrepresented from the campaign's materials:

- a) One of the side effects of Trulance—like other CIC medications—is diarrhea, ¶¶30, 32-33;
- b) Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea, ¶¶30, 32, 40-42, 45-46;
- c) Synergy possessed no evidence that Trulance had a superior side-effect profile, including with respect to diarrhea, because no adequate and well-controlled head-to-head trial data existed to support that comparison, ¶¶40-42, 45; and

- d) The data Synergy possessed from clinical trials of Trulance and Linzess was not comparable for the additional reason that Trulance’s Phase 3 trials recorded/defined diarrhea in a different manner than Linzess’ trials did, *i.e.*, only if the Trulance patient subjectively found the diarrhea “bothersome,” ¶¶30, 32, 46.

**H. Express Scripts Excludes Trulance From Its National Preferred Formulary But Covers Linzess And Amitiza**

65. Express Scripts is the “largest independent manager of pharmacy benefits in the United States and one of the country’s largest pharmacies, serving more than 85 million people.” Express Scripts, Member Website, <https://www.express-scripts.com/>. Pharmacy benefits managers (“PBMs”), such as Express Scripts, “administer prescription drug plans for” people “who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.” PCMA, *Our Industry*, <https://www.pcmanet.org/our-industry/>. Put another way, PBMs act as “middlemen . . . designed to process prescription medication claims (for a small fee per claim) for insurance companies and plan sponsors[.]” Nov. 14, 2017 Pharmacy Times Article, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*.

66. Each year, Express Scripts releases a National Preferred Formulary Exclusions list. *See, e.g.*, Express Scripts, *2018 National Preferred Formulary Exclusions*.<sup>25</sup> A formulary is “a continually updated list of prescription drugs approved for reimbursement by the PBM’s

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<sup>25</sup> [https://www.express-scripts.com/art/open\\_enrollment/DrugListExclusionsAndAlternatives.pdf](https://www.express-scripts.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf).

payer client.” PCMA, *What Is A Formulary?*.<sup>26</sup> If a drug is an excluded medication, then that drug will not be covered by Express Scripts or its clients and, “in most cases” the patient will have to “pay the full retail price.” Express Scripts, *2018 National Preferred Formulary Exclusions*. Furthermore, doctors are less likely to prescribe medication that is excluded from a formulary. See, e.g., J. Bruce Leavitt, PM360, *Your Drug Landed on a Formulary Exclusion List: Where Do You Go From Here?* (published Aug. 9, 2017) (noting that landing on an exclusion list is “a real problem for a marketer” and that health care providers “prescribe less of an excluded drug—even to patients whose access has not been restricted”).<sup>27</sup>

67. Express Scripts’ National Preferred Formulary ***includes “all clinically superior medications,” but excludes “me-too<sup>28</sup> options that have no added clinical benefit but have higher costs.***” Express Scripts, *How We Build a Formulary* (July 26, 2016).<sup>29</sup> Express Scripts bases its formulary decisions on “objective evaluations from independent physicians.” *Id.* These independent physicians, who are not employed by Express Scripts, are selected to form a National Pharmacy & Therapeutics Committee (“PTC”), which evaluates the drugs. *Id.* PTC members are also vetted for conflicts of interest. *Id.* If the PTC recommends that a medicine be included, then “Express Scripts is required to include” that medication in its formulary. *Id.*

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<sup>26</sup> <https://www.pcmanet.org/pcma-cardstack/what-is-a-formulary/>.

<sup>27</sup> <https://www.pm360online.com/your-drug-landed-on-a-formulary-exclusion-list-where-do-you-go-from-here/>.

<sup>28</sup> “Me-too” drugs “are very similar to existing drugs in the same category. They often have only slight differences in the way their chemistry is designed and in how they work.” Optum, *The Growth of “Me Too” Drugs*, <https://www.optum.com/resources/library/metoodrugs.html>.

<sup>29</sup> <http://lab.express-scripts.com/lab/insights/drug-options/how-we-build-a-formulary>.

68. Additionally, Express Scripts' internal clinical review body, the Therapeutic Assessment Committee ("TAC"), which consists of clinical pharmacists and physicians, reviews specific medications following FDA approval using medical literature and published clinical trial data. *Id.* Express Scripts also considers recommendations from the TAC. *Id.*

69. Lastly, the third committee Express Scripts engages is the Value Assessment Committee ("VAC"). *Id.* The VAC consists of Express Scripts' employees from formulary management, product management, finance and clinical account management. *Id.* If a drug is considered optional—the "medication is safe and effective for its indicated use" but the PTC considers it optional because there are clinically-equivalent alternatives available—the VAC makes recommendations on the value of the drug by considering factors, including cost. *Id.* The VAC's recommendation is then sent back to the PTC for final approval. *Id.*

70. Accordingly, *if Synergy's Trulance was in fact superior to its competitors, then it would be included in Express Scripts National Preferred Formulary, and not excluded.* However, on July 31, 2017, *Express Scripts published its 2018 National Preferred Formulary, which excluded Trulance but included Linzess and Amitiza as "preferred alternatives."* See Express Scripts, 2018 National Preferred Formulary (published July 31, 2017).

71. On this news, Synergy's share price fell \$0.18 per share, or approximately 4.4% from the previous trading day's closing price of \$4.06, to close at \$3.88 per share on July 31, 2017.

#### **I. Synergy Discloses A July 2017 Slowdown In Trulance's Prescription Growth Rate And Synergy's Massive Cash Burn**

72. On August 9, 2017, after market close, Synergy filed with the SEC its Quarterly Report on Form 10-Q for the second quarter of 2017. Synergy, Quarterly Report on Form 10-Q (Aug. 9, 2017). The Company revealed that, while it generated \$2.3 million in Trulance net

sales, Synergy expended \$73.6 million, leaving the Company with only \$82 million in cash or cash equivalents. *Id.* at 3-4. With only \$82 million in cash, and a net cash burn rate of approximately \$71.3 million (\$73.6 million minus the \$2.3 million in Trulance sales) in the previous quarter, Trulance's revenues could not fully fund Synergy's operations beyond the next quarter.

73. The Company also issued a press release regarding its second quarter financial results quoting Defendant Gemignani, who stated that the Company was "evaluating financing options that will provide flexibility and allow [Synergy] to continue to execute on [its] business objectives." Aug. 9, 2017 Synergy Press Release, *Synergy Pharmaceuticals Reports Second Quarter 2017 Financial Results and Business Update*.

74. That same day, after the market closed, Synergy released a slideshow presentation summarizing its quarterly performance, along with Trulance prescription trends ("2Q 2017 Presentation"). The 2Q 2017 Presentation revealed a slowdown in the pace of Trulance prescriptions. For the month of July 2017, the average weekly growth rate of Trulance prescriptions was 4.46%, as compared to the 8.5% average weekly growth rate in June. *See* Aug. 9, 2017 Synergy Presentation, *Corporate Presentation* at 27.

75. On this news, Synergy's share price fell \$0.46 per share, or approximately 13.03% from the previous trading day's closing price of \$3.53, to close at \$3.07 per share on August 10, 2017.

**J. Defendants Make False And/Or Misleading Statements About The \$300 Million CRG Loan And Omit Its \$128 Million Cash Condition Precedent**

76. Due to the substantial expense and risk involved, small drug development companies like Synergy typically partner with a "Big Pharma" company during the regulatory review process to ensure adequate funding for that process, as well as the subsequent sales and

marketing of the drug. In fact, the market-leading CIC drug Linzess was commercialized by such a partnership in that Ironwood, the drug's inventor, partnered with the much larger Allergan to ensure sufficient funding.

77. In an October 25, 2018 press release, Synergy disclosed that, in April 2015, prior to the FDA approval and launch of Trulance, the Company hired an advisory firm to engage external parties and evaluate all strategic options available to the Company, including partnerships in the United States and abroad, as well as a possible sale of the Company. Ultimately, Synergy claimed in the press release, there were no offers to acquire the Company and no satisfactory partnership opportunities emerged in this evaluation. As a result, Synergy determined to pursue a go-it-alone strategy to commercialize Trulance and retain 100% of the rights to the drug.<sup>30</sup>

78. The commercialization of Trulance would require substantial capital. On January 31, 2017, after securing FDA approval for Trulance, Synergy announced a secondary stock offering of 20 million new shares at a price of \$6.15 per share to “fund its commercialization activities related to Trulance,” among other things.<sup>31</sup> As a result of the offering, Synergy's outstanding shares were diluted by more than 11%.

79. On May 3, 2017, Synergy and Defendants Jacob and Hamilton participated in the Deutsche Bank Health Care Conference. At the conference, Defendant Jacob touted the Company's strategy for the commercialization of Trulance: “We invented this drug, and we

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<sup>30</sup> [https://www.sec.gov/Archives/edgar/data/1347613/000110465918063974/a18-37215\\_1ex99d1.htm#Exhibit99\\_1\\_021153](https://www.sec.gov/Archives/edgar/data/1347613/000110465918063974/a18-37215_1ex99d1.htm#Exhibit99_1_021153)

<sup>31</sup> [https://www.sec.gov/Archives/edgar/data/1347613/000110465917006165/a17-2527\\_38k.htm](https://www.sec.gov/Archives/edgar/data/1347613/000110465917006165/a17-2527_38k.htm); [https://www.sec.gov/Archives/edgar/data/1347613/000110465917006165/a17-2527\\_3ex99d1.htm](https://www.sec.gov/Archives/edgar/data/1347613/000110465917006165/a17-2527_3ex99d1.htm).

have been focused on developing this drug, and we have taken this drug all the way through its clinical development entirely on our own. We believe passionately in this drug and in its characteristics, and we wanted to control 100% of the worldwide rights.”

80. In the Company’s Quarterly Report on Form 10-Q filed with the SEC on May 10, 2017, Synergy updated the market on its strategy, disclosing that the Company would commercialize Trulance through third party contract manufacturers and employ a cadre of approximately 250 sales representatives fully deployed throughout the United States. Synergy further disclosed that, in the first quarter of 2017, it had incurred over \$62.7 million in expenses,<sup>32</sup> including almost \$42 million in selling, general and administrative (“SG&A”) expenses. With regard to the SG&A expenses, Synergy noted: “Selling, general and administrative expenses increased approximately \$35.5 million or 554.7%, to \$41.9 million for the Current Year Quarter from approximately \$6.4 million for the Prior Year Quarter. These increased expenses primarily reflect the cost of building a Commercial Organization as part of our product launch of TRULANCE in the Current Year Quarter. These costs include commercial preparedness and planning expenses including an approximately \$26.6 million increase in marketing and sales expenses, a \$2.2 million increase in consulting expenses, a \$3.7 million increase in employee compensation and benefits costs, and a \$0.6 million increase in stock compensation expense.”

81. In its Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017, Synergy reported that its expenses soared to nearly \$73.6 million,<sup>33</sup> depleting the Company’s

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<sup>32</sup> These expenses include the Research and Development and SG&A expenses that Synergy reported during that quarter.

<sup>33</sup> These expenses include the Research and Development and SG&A expenses that Synergy reported during that quarter.

cash reserves to just less than \$82 million. The Company reported that its SG&A expenses rose to nearly \$50.7 million: “Selling, general and administrative expenses increased approximately \$40.4 million or 392.2%, to \$50.7 million for the three months ended June 30, 2017 from approximately \$10.3 million for the three months ended June 30, 2016. These increased expenses reflect primarily marketing and promotional activities as part of our product launch of TRULANCE in the first quarter of 2017. These costs include commercial preparedness and planning expenses including an approximately \$23.1 million increase in marketing and sales expenses, a \$4.7 million increase in employee compensation and benefits costs, and a \$11.5 million increase in stock compensation expense. The increase in stock compensation expense was primarily driven by a \$6.6 million charge related to the immediate vesting due to a modification of previously granted Change of Control options, and a \$2.8 million charge related to stock option modifications for terminated employees.” The Company further disclosed that “Synergy will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels.”

82. On September 5, 2017, the Company announced that it had closed on a \$300 million debt financing structured as senior secured loans from CRG LP (“CRG”), a healthcare focused investment firm. The Company reported that the CRG Loan granted Synergy an upfront funding of \$100 million, an additional \$100 million on or before February 28, 2018, and two additional tranches of \$50 million each on or before March 29, 2019 (the “CRG Loan”). Sept. 5, 2017 Synergy Press Release, *Synergy Pharmaceuticals Secures \$300 Million Debt Financing*.<sup>34</sup>

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<sup>34</sup> <https://ir.synergypharma.com/press-releases/detail/1852/synergy-pharmaceuticals-secures-300-million-debt-financing>.

83. Unbeknownst to investors, however, Defendants failed to disclose the existence of the CRG Loan's Cash Condition Precedent: in order to secure the second tranche of \$100 million financing, the Company would need to have cash or cash equivalents "equal to or greater than \$128 million" as of January 31, 2018. *See* Term Loan Agreement (Ex. 10.2 to Form 10-Q, filed with the SEC on Nov. 9, 2017) ("Term Loan Agreement") at §§1.01, 6.02 ). The undisclosed Cash Condition Precedent states:

"Second Tranche Borrowing Milestone" means that, *as of January 31, 2018, Borrower shall have an amount of cash and Permitted Cash Equivalent Investments* (which for greater certainty shall not include availability under any undrawn credit lines) *equal to or greater than \$128,000,000 that* (i) is held in one or more accounts over which the Secured Parties have a perfected security interest, (ii) is otherwise unencumbered (other than pursuant to a Loan Document), (iii) *consists of funds from operations or other sources of financing that do not include any proceeds of borrowings from any third party incurred after the date hereof (other than the Lenders under this Agreement)*, and (iv) does not comprise funds that, as of the date of the notice delivered pursuant to this definition, must be applied (x) pursuant to Section 3.03(b) to repay any Obligations or (y) pursuant to any agreement governing Permitted Priority Debt to repay any Permitted Priority Debt[.]

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6.02 Conditions To Subsequent Borrowings. . . . (ii) Amount of Borrowing. The amount of such Borrowing shall equal \$ 100,000,000. (iii) Borrowing Milestone. ***The Second Tranche Borrowing Milestone shall have occurred.***

*Id.* The Cash Condition Precedent explicitly excludes cash from other debt borrowings, meaning that the cash counting toward to the \$128 [million] Second Tranche Borrowing Milestone can only come from operations, *i.e.*, Trulance revenues, "or other sources[.]" *i.e.*, equity. *See id.*

84. Defendants, however, chose to omit the existence of the Cash Condition Precedent from their disclosures, electing instead to tout the loan as "non-dilutive," available if and when needed, and as funding Synergy's commercialization of Trulance "through 2019" when, in fact, the Cash Condition Precedent prevented funds from the CRG Loan from being

available to Synergy if and when needed because meeting the Cash Condition Precedent by January 31, 2018 all but necessitated a dilutive offering of shares.

85. As Synergy later revealed, for the third quarter ending in September—the same month it entered into the CRG Loan—Synergy had approximately \$117.8 million in cash, which fell short of the \$128 million Cash Condition Precedent. *See* Synergy Form 10-Q for Q3 2017 at 3, filed with the SEC on Nov. 9, 2017. For the third quarter, Synergy reported expenses of over \$47.7 million,<sup>35</sup> with SG&A expenses amounting to almost \$44 million. *See id.* at 4.

86. Synergy was rapidly burning cash, and its revenue, *i.e.*, its sales of Trulance, was insufficient to meet the cash amount required for the Cash Condition Precedent without more. Just a month before its announcement of the Loan, Synergy reported that it had \$81 million in cash for the quarter ending in June, but had spent almost \$74 million to reap \$2.3 million worth of Trulance net sales for that quarter. *See* Synergy Form 10-Q for Q2 2017 at 3-4, filed with the SEC on Aug. 9, 2017. As shown in the table below, during the first three quarters of 2017, which include the month Synergy announced the CRG Loan, ***Synergy burned an average of \$61.3 million per quarter***, while reaping an average of only \$2.5 million on Trulance sales over the same period.

Quarter	Expenditures <sup>36</sup>	Trulance Net Sales
First quarter ending March 30, 2017	\$62.7 million	\$98,000

<sup>35</sup> The \$47.7 million consists of the Research & Development and SG&A expenses Synergy reported for that quarter.

<sup>36</sup> The expenditures listed in this table consist of the Research & Development and SG&A expenses Synergy reported for those quarters.

Second quarter ending June 30, 2017	\$73.6 million	\$2.3 million
Third quarter ending September 30, 2017	\$47.7 million	\$5 million

See Synergy Form 10-Q for Q1 2017 at 4, filed with the SEC on May 10, 2017; Synergy Form 10-Q for Q2 2017, filed with the SEC on Aug. 9, 2017; Synergy Form 10-Q for Q3 2017 at 4, filed with the SEC on Nov. 9, 2017.

87. Given the undisclosed \$128 million Cash Condition Precedent of the CRG Loan and Synergy's cash position at the time it announced the CRG Loan—approximately \$117.8 million in cash, a \$61.3 million average quarterly cash burn, and an average of \$2.5 million quarterly Trulance revenues—a dilutive equity offering had already become all but necessary to meet the Cash Condition Precedent and to access the second tranche of \$100 million provided by the Loan. Even if Synergy had \$128 million—or more—on September 5, 2017, Synergy's cash burn rate of \$61.3 million meant that an equity dilution was already all but necessary to fulfill the Cash Condition Precedent in order to have \$128 million on January 31, 2018 and satisfy the Cash Condition Precedent. Trulance's revenues, which averaged \$2.5 million per quarter, paled in comparison to the amounts being expended to generate those revenues. Indeed, Synergy continued to burn much more cash than it obtained from Trulance sales in the fourth quarter of 2017 ending December 31, 2017, with expenses totaling approximately \$38.2 million<sup>37</sup> and Trulance net sales totaling \$9.4 million. See Ex. 99.1 to Synergy Form 8-K, filed with the SEC

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<sup>37</sup> These expenses include the Research and Development and SG&A expenses that Synergy reported during that quarter.

on Mar. 1, 2018. All told, for fiscal 2017, Synergy incurred over \$222 million in expenses, including over \$181.8 million in SG&A expenses.

88. Thus, when Synergy announced the Loan—with approximately \$117.8 million in cash in September, an average quarterly cash burn of \$61.3 million for 2017, and average Trulance revenues of \$2.5 million—a dilutive stock offering was already all but required to meet the \$128 million Cash Condition Precedent given that Synergy was cash flow negative and the Company itself recognized it would not be cash flow breakeven until 2019. *See Synergy Q2 2017 Business Update Call on Sept. 7, 2017, Bloomberg Transcript at 2-3.*

89. Despite these facts, Synergy began misrepresenting the nature and impact of the CRG Loan on September 5, 2017, when the Company issued a press release titled “Synergy Pharmaceuticals Secures \$300 Million Debt Financing,” which was reproduced as Exhibit 99.1 to a Current Report on Form 8-K signed by Defendant Jacob filed with the SEC that same day. In the press release and Ex. 99.1 to the Form 8-K filed that day, Synergy, Defendant Gemignani, and Defendant Jacob stated in relevant part:

Synergy Pharmaceuticals Inc. (NASDAQ: SGYP), announced today that the Company has closed on a \$300 million debt financing structured as senior secured loans from CRG LP, a healthcare focused investment firm, and its lender syndicate.

***“This non-dilutive financing enhances our cash position and provides us with financial flexibility to continue to execute on the launch of Trulance and achieve our business objectives, which we are confident will ultimately maximize long-term shareholder value,”*** said Gary Gemignani, EVP and Chief Financial Officer of Synergy Pharmaceuticals Inc. ***“The structure of this financing provides us with access to capital for support of our commercialization of Trulance and funds our current plans for the Company through 2019 when, based on our current assumptions, we expect to be cash flow breakeven.”***

90. The statements by Synergy, Defendants Gemignani and Jacob in ¶89 above were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) The CRG Loan's Cash Condition Precedent required Synergy to have \$128 million in cash or cash equivalents as of January 31, 2018 in order to obtain the second tranche of \$100 million in financing, ¶¶82-83;
- b) Synergy's available cash, cash-burn rate, and Trulance revenues were insufficient to meet the \$128 million Cash Condition Precedent, ¶¶83-88;
- c) Synergy needed to issue shares to meet the Cash Condition Precedent which would dilute shareholders' equity interests, ¶¶83-88, 104, 109; and
- d) As a result, the CRG Loan could not be accurately described as "non-dilutive" without meaningful disclosure of the highly material Cash Condition Precedent, which all but necessitated that Synergy conduct another dilutive secondary offering of shares, ¶¶83-88, 104, 109.

91. That same day, Synergy filed with the SEC a Current Report on Form 8-K, signed by Defendant Jacob, which stated:

The Loan Agreement provides for a \$300.0 million term loan facility to the Company, \$100.0 million of which was borrowed at closing (the "Initial Term Loan"). ***The Loan Agreement provides for future borrowings, subject to the satisfaction of certain financial and revenue milestones and other borrowing conditions as follows:*** (i) an additional \$100.0 million on or before February 28, 2018 (the "Second Tranche Term Loan"), and (ii) up to two additional tranches of up to \$50.0 million each on or before March 29, 2019 (together with the Initial Term Loan and the Second Tranche Term Loan, the "Term Loans"). The Company expects to use the proceeds of the Initial Term Loan and any remaining Term Loans for commercialization of its Trulance™ (plecanatide) product and general working capital and general corporate purposes, including fees, costs and expenses incurred in connection with the Loan Agreement. The Term Loans have a maturity date of June 30, 2025, unless earlier prepaid.

\* \* \*

In addition, ***the Loan Agreement requires the Company to comply with a minimum market capitalization covenant, maintain its status as a national exchange listed public company, a daily minimum liquidity covenant and an annual revenue requirement based on the sales of Trulance.***

92. The statements by Defendant Jacob and Synergy in ¶¶91 above were false and/or misleading when made because the following facts were misrepresented or omitted:

- a) The CRG Loan's Cash Condition Precedent required Synergy to have \$128 million in cash or cash equivalents as of January 31, 2018 in order to obtain the second tranche of \$100 million in financing, ¶¶82-83;
- b) Synergy's available cash, cash-burn rate, and Trulance revenues were insufficient to meet the \$128 million Cash Condition Precedent, ¶¶83-88;
- c) Synergy needed to issue shares to meet the Cash Condition Precedent which would dilute shareholders' equity interests, ¶¶83-88, 104, 109; and
- d) As a result, the description of the CRG Loan provided in the 8-K is misleading and omits material information, ¶¶83-88, 104, 109.

93. Analysts responded positively to the news of the CRG Loan. On the same day it was announced, Seeking Alpha, a financial news site, published an analysis from analyst "Life Sciences Millennial" who emphasized that further shareholder dilution would be avoided by the Loan:

***Most importantly, the debt financing deal is non-dilutive.*** Synergy investors have experienced dilution, like any other company's investors, a few times. With Synergy's stock price declining and sitting at \$3 per share for the last couple weeks, it made it unlikely that more dilution was on the way. ***The CFO also mentioned that the company has enough cash through 2019,*** where the company would also break-even.

Sept. 5, 2017 Life Sciences Millennial Article, SeekingAlpha.com, *Synergy Pharma: It Takes Money To Make Money*.<sup>38</sup>

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<sup>38</sup> <https://seekingalpha.com/article/4104279-synergy-pharma-takes-money-make-money>.

94. Also on the same day, BTIG analyst Timothy Chiang stated that the Loan is a net positive, and provides Synergy with the funding needed to execute its strategy to commercialize Trulance. As a result, BTIG maintained a Buy Rating for SGYP at an \$11 Target Price:

300M Debt Deal with CRG LP Should Remove Near Term Financing Overhang. Based on our current estimates for Trulance sales and forecasts for operating expenses, ***this debt deal (which is structured as senior secured loans with a June 30, 2025 maturity at a 9.5% annual interest rate) will provide the Co. with sufficient funding for the commercial ramp of Trulance for the next several years.*** We believe ***this term loan agreement provides the Co. the necessary funds to successfully ramp Trulance into a meaningful product.***

Sept. 5, 2017 BTIG Analyst Report, *Term Loan Financing Arrangement with CRG LP a Net Positive, In Our View*, at 1.

95. On September 7, 2017, the Company hosted a conference call to discuss the Company's financial results for the second quarter of 2017. On the conference call, Defendants Jacob, Gemignani, and Hamilton stated in relevant part:

[Gary Jacob]: And on Tuesday this week, we announced that we secured a debt financing that provides us with access of up to \$300 million in additional capital. ***This financing strengthens our cash position and provides us with financial flexibility to continue to execute on the launch of Trulance and achieve our key business priorities,*** which we are confident will ultimately maximize shareholder value.

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***The debt financing that we just announced on Tuesday provides access to additional capital if and when we need it, and gives us the greatest flexibility to execute on our corporate strategy.*** In conjunction with this financing, we are continuing to evaluate opportunities to improve expense management with the goal of transitioning the company to cash flow positive.

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[Gary Gemignani]: Turning to slide 9. As Gary just mentioned, we achieved an important milestone this week when we announced that the company secured up to \$300 million in the debt financing structured as a senior secured loan from CRG, a health care-focused investment firm. ***This non-dilutive financing enhances our cash position and provides us with financial flexibility to continue to execute on the launch of Trulance and achieve our business objectives, which Gary just outlined for you. The structure of***

**the deal provides us with access to additional capital if and when we need it, to support the product launch and to take the company through 2019 when based on our current assumptions we expect Synergy to be cash flow breakeven.**

The first tranche of \$100 million was funded upon the execution of the loan documents. **Under the terms of the agreement, we have access to an additional \$100 million on or before February 28, 2018 and up to two additional tranches of up to \$50 million each on or before March 29, 2019, subject to the satisfaction of certain financial and revenue milestones and other borrowing conditions.**

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While we are not providing revenue or cash burn guidance at this stage, **we are confident in our ability to meet all of the performance milestones stated under the terms of this agreement, and we will have access to additional capital if and when we need it.**

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Looking at SG&A. We're evaluating opportunities to improve cost efficiency measures, and we'll continue to focus investments in key commercial activities that continue to drive Trulance demand and ensure long-term success of the franchise and ultimately drive profitability. We are currently evaluating the 2018 business plans, and we'll provide expense guidance in future periods. In Trulance, we have a high-value asset and a large and growing market, supported by a strong and highly experienced commercial team. **With the capital from this financing and continued success of the launch, we are confident we are well positioned to effectively maximize the value of Trulance and add significant value to the company and its shareholders.**

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[Timothy Chiang, analyst at BTIG]: And just maybe one follow-up for Gary [Gemignani]. In terms of the CRG deal, I noticed that it is somewhat of a tiered deal in terms of the timing of the debt or the cash that you received. And I just wanted to circle back and ask you how confident are you that you'll hit the milestones or the financial targets that CRG has set for you.

[Gary Gemignani]: Tim. Thanks. **Look, we're very confident.** In fact, the way we structured this deal, we looked at numerous types of structures and with the goal of getting the right size, the lowest cost to capital and structure in a way where our debt service would be as low as possible in the earlier years so that we could put the cash to work on funding our commercial launch. **So we're—again, we've had the CRG obviously with extreme amounts of diligence and we are—as we constructed the tiers, we're very comfortable we'll be able to meet all of the commitments.**

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[William Tanner, analyst at Cantor Fitzgerald]: That's fine. And maybe, the last one is if you – now that you've got financial flexibility, if there is something more [ph] that you wanted that you felt like you needed or I don't know if there's something right now that you feel like you need it [ph] and I think you mentioned you've got a DTC campaign. But just is there something more that the recent transaction [the CRG Loan] gives you the flexibility to do that might move the needle a little bit more, or is this still just kind of getting the base business going and then seeing where you might move the pieces around thereafter?

[Troy Hamilton] **Yeah.** One of the things that we talk about often is this theme of we're in launch mode. And we want to stick to our core strategies. We had this strategy developed a year-and-a-half ago, where we wanted to focus on the most productive prescribers. And at least during launch mode, we will continue with that. And maybe down the road, three, four years down the road, in terms of evaluating different options maybe that will come into play. ***But for right now we're pretty much because of the funding, it feeds our strategies and tactics and activities we already have in place and plan in the next year to two years.***

Synergy Q2 2017 Business Update Call on Sept. 7, 2017, Bloomberg Transcript at 2-3, 8, 11 .

96. The statements by Synergy, Defendants Jacob, Gemignani, and Hamilton in ¶95 above were false and/or misleading when made because the following facts were misrepresented or omitted:

- a) The CRG Loan's Cash Condition Precedent required Synergy to have \$128 million in cash or cash equivalents as of January 31, 2018 in order to obtain the second tranche of \$100 million in financing, ¶¶82-83;
- b) Synergy's available cash, cash-burn rate, and Trulance revenues were insufficient to meet the \$128 million Cash Condition Precedent, ¶¶83-88;
- c) Synergy needed to issue shares to meet the Cash Condition Precedent which would dilute shareholders' equity interests, ¶¶83-88, 104, 109;
- d) As a result, the CRG Loan could not be accurately described as "non-dilutive" without meaningful disclosure of the highly material Cash Condition Precedent,

which all but necessitated that Synergy conduct a dilutive secondary offering of shares, ¶¶83-88, 104, 109; and

- e) The CRG Loan was subject to a material Cash Condition Precedent that the Company could not satisfy at the time the statement was made and that meeting the Cash Condition Precedent by January 31, 2018, as required to access the second tranche of the Loan, all but necessitated a dilutive offering of shares. As such, the funding from the CRG Loan was not available “if and when” needed by Synergy, ¶¶82-88, 104, 109.

97. Defendants’ statements led investors—and analysts—to conclude that the CRG Loan would fund the Company’s activities, including the commercialization strategy for Trulance, through 2019. *See, e.g.*, Sept. 5, 2017 Canaccord Genuity Analyst Report, *Securities \$300M in debt financing, overhang removed*, at 1 (“Based on cash flow analysis, we expect the debt financing to sustain the company through 2019, which is highly encouraging.”); Sept. 5, 2017 BTIG Analyst Report, *Term Loan Financing Arrangement with CRG LP a Net Positive, In Our View*, at 1 (“Based on our current estimates for Trulance sales and forecasts for operating expenses, this debt deal (which is structured as senior secured loans with a June 30, 2025 maturity at a 9.5% annual interest rate) will provide the Co. with **sufficient funding for the commercial ramp of Trulance for the next several years.**”).

98. On October 6, 2017, SeekingAlpha published an analysis by John Engle expressing confidence in Synergy’s future, listing Trulance’s side-effect superiority over Linzess, its solid financials based on the CRG Loan, and the prevention of dilution by securing funding for the next four quarters as primary reasons for that confidence:

Linzess continues to be the big dog of CIC treatment. . . . Trulance stands apart from its main competitor. . . . More importantly the rates of diarrhea . . . are radically lower in Trulance than Linzess. . . .

At the end of Q2, there was a bit of uncertainty surrounding Synergy's near-term financial health. The company reported a net loss of \$73.9 million and a cash balance of \$82 million. The uncertainty was dispelled quite resoundingly in early September when Synergy announced it had secured \$300 million in debt financing. While the market through [sic] a slight tantrum at the time, the decision was sound. ***It prevented dilution and brought in enough cash to continue operations for four quarters at the current burn rate.***

Oct. 6, 2017 John Engle Article, Seeking Alpha, *After A Stumble, Synergy Pharmaceuticals Is Poised To Rise*.<sup>39</sup>

**K. Synergy Discloses Third Quarter Slowdown In Trulance's Prescription Growth Rate And Misleads Investors Further Regarding The Loan**

99. On November 9, 2017, after the market had closed, Synergy released its earnings for the third quarter of 2017. Nov. 9, 2017 Synergy Press Release, *Synergy Pharmaceuticals Reports Third Quarter 2017 Financial Results and Business Update*.<sup>40</sup>

100. In the press release, Defendants disclosed that Synergy had \$117.8 million in cash and cash equivalents at the end of the quarter, net cash used in operating activities was \$59.3 million, and SG&A expenses totaled \$44 million. Defendants nevertheless continued to tout the CRG Loan as non-dilutive, without disclosing the Cash Condition Precedent and its terms, on a November 9, 2017 conference call discussing the Company's quarterly results, which started at 4:30 p.m. During the call, Defendant Gemignani stated that the CRG Loan "***provides [Synergy]***

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<sup>39</sup> subscribers at <https://seekingalpha.com/article/4112088-stumble-synergy-pharmaceuticals-poised-rise>.

<sup>40</sup> <https://ir.synergypharma.com/press-releases/detail/1858/synergy-pharmaceuticals-reports-third-quarter-2017>.

*with access to multiple tranches of up to an additional \$200 million in non-dilutive capital should we choose to draw upon it.*” Defendant Gemignani further stated:

*While I cannot comment on specific conditions required to access the additional tranches beyond what’s publicly disclosed, I can tell you that we are confident in our ability to meet the conditions that will allow us to access to the additional capital if and when we need it.*

Synergy Q3 2017 Earnings Call on Nov. 9, 2017, Bloomberg Transcript at 5 .

101. The statements by Synergy and Defendant Gemignani in ¶100 above were false and/or misleading when made because the following facts were omitted or misrepresented:

- a) The CRG Loan’s Cash Condition Precedent required Synergy to have \$128 million in cash or cash equivalents as of January 31, 2018 in order to obtain the second tranche of \$100 million in financing, ¶¶82-83;
- b) Synergy’s available cash, cash-burn rate, and Trulance revenues were insufficient to meet the \$128 million Cash Condition Precedent, ¶¶83-88;
- c) Synergy needed to issue shares to meet the Cash Condition Precedent which would dilute shareholders’ equity interests, ¶¶83-88, 104, 109;
- d) Synergy was already planning the offering necessary to satisfy the Cash Condition Precedent, which it announced four days later, ¶¶104, 143-44;
- e) As a result, the CRG Loan could not be accurately described as “non-dilutive” without meaningful disclosure of the highly material Cash Condition Precedent, which all but necessitated that Synergy conduct a dilutive secondary offering of shares, ¶¶83-88, 104, 109;
- f) Defendant Gemignani’s statement that the CRG Loan “*provides [Synergy] with access to multiple tranches of up to an additional \$200 million in non-dilutive capital should we choose to draw upon it*” misrepresented that it was Synergy’s

decision whether or not to draw upon the loan and that there would be no impediment caused by any borrowing conditions or terms from it doing so. In fact, the highly material Cash Condition Precedent prevented Synergy from drawing upon the Loan without undergoing the substantial planning and expense for a dilutive share offering, ¶¶83-88, 104, 109; and

- g) The CRG Loan was subject to a material Cash Condition Precedent that the Company could not satisfy at the time the statement was made and that meeting the Cash Condition Precedent by January 31, 2018, as required to access the second tranche of the Loan, all but necessitated a dilutive offering of shares. As such, the funding from the CRG Loan was not available “if and when” needed by Synergy, ¶¶83-88, 104, 109.

102. That day, the Company also released a slide-show presentation detailing the Company’s “Key Performance Metrics” (the “3Q 2017 Presentation”). Nov. 9, 2017 Synergy Presentation, *3Q 2017 Update*. The 3Q 2017 Presentation revealed a dramatic slowdown in Trulance prescriptions, as in September 2017, Trulance prescriptions grew only 4.4%. *Id.* at 9. The 3Q 2017 Presentation also revealed that September 2017 was the fourth consecutive month in which the number of Trulance prescriptions written by each individual Trulance prescriber had decreased. *Compare id.* at 9 (monthly prescriptions), *with id.* at 10 (monthly prescribers).

103. On this news, Synergy’s share price fell \$0.25 per share, or approximately 8.42% from the previous trading day’s closing price of \$2.97, to close at \$2.72 per share on November 10, 2017.

**L. Synergy Discloses Dilution Of Shareholders Via A New Public Offering**

104. On November 13, 2017, before the market opened, Synergy filed with the SEC an S-3 Registration Statement for the issuance of new shares in the Company. Synergy Form S-3, filed on Nov. 13, 2017. The Form S-3 was signed by Defendants Jacob and Gemignani, among others. In a press release, Synergy revealed that it was publicly offering 21,705,426 shares of its common stock together with warrants to purchase an aggregate of 21,705,426 shares of common stock at a combined price to the public of \$2.58 per share, or an aggregate offering price of approximately \$56 million. Nov. 13, 2017 Synergy Press Release, *Synergy Pharmaceuticals Announces Pricing of Offering of Common Stock and Warrants*.<sup>41</sup> Synergy represented that a “final prospectus supplement and accompanying prospectus will be filed with the SEC.” *Id.* Contrary to its prior representations that the CRG Loan would fully fund the Company’s operations through 2019, the Company now explained that the proceeds from the offering would help “fund its commercialization activities related to Trulance and for working capital and other general corporate purposes.” *Id.*

105. On this news, Synergy’s share price fell \$0.28 per share, or approximately 10.3% from the previous trading day’s closing price of \$2.72, to close at \$2.44 per share on November 13, 2017.

106. On November 14, 2017, before the market opened, BTIG issued an analyst report lowering its price target for Synergy shares to \$7 from \$11 per share, a drop of over 36%, as it pieced together that Synergy’s recent public offering was tied directly to the \$128 million Cash Condition Precedent. Nov. 14, 2017 BTIG Analyst Report, *Synergy Pharmaceuticals, Inc.*:

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<sup>41</sup> <https://ir.synergypharma.com/press-releases/detail/1859/synergy-pharmaceuticals-announces-pricing-of-offering-of>.

*Lowering PT to \$7 (From \$11); Factoring in Risk of Additional Equity Financings By Late CY18 / Early CY19 (Nov. 14, 2017); see also Streetinsider.com, Synergy Pharmaceuticals (SGYP) PT Lowered to \$7 at BTIG; Factoring Risk of Additional Equity Financings by Late CY18/Early CY19 (published at 6:53 a.m.). BTIG reported that Synergy’s “recent equity financing . . . was a surprise as we did not expect the Co. to need to raise additional capital as a requirement to gaining access to the second \$100 [million] in funds from its recently announced term loan agreement with CRG LP.” Id.*

107. Also on November 14, 2017, John Engle published a report on Seeking Alpha announcing that he found Defendants’ previous statements to be “*obfuscation . . . bordering on deliberate misdirection*”:

The move was doubly strange, not having been telegraphed at all during the earnings call at the start of the month, and seemingly unnecessary given current cash reserves and access to non-dilutive debt financing.

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What Synergy did not disclose during conference calls, nor bother to highlight except on a 10-Q report, was that this loan was subject to the company having a certain amount of cash at the end of January 31st to obtain the next tranche. I am struck in particular by a statement from CFO Gary Gemignani during the last earnings call:

[Gemignani:] ‘Under the terms of the agreement, we have access to an additional \$100 million on or before February 28, 2018 and up to two additional tranches of up to \$50 million on or before March 29, 2019 subject to certain conditions. While I cannot comment on specific conditions required to access the additional tranches beyond what’s publicly disclosed, I can tell you that we are confident in our ability to meet the conditions that will allow us to access to the additional capital if and when we need it.’ *That looks a lot like obfuscation in hindsight, bordering on deliberate misdirection.*

Nov. 14, 2017 John Engle Report, Seeking Alpha, *Synergy Pharmaceuticals: A Misjudged Secondary Offering*.<sup>42</sup>

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<sup>42</sup> <https://seekingalpha.com/article/4124607-synergy-pharmaceuticals-misjudged-secondary-offering>.

108. That day, Synergy's share price fell another \$0.41 per share, or approximately 16.8% from the previous trading day's closing price, to close at \$2.03 per share on November 14, 2017.

109. That day, after market close, Synergy filed with the SEC a final Prospectus on Form 424B5 for the dilutive public offering. *See* Synergy Form 424B5 filed with the SEC on Nov. 14, 2017.

110. Like BTIG and analysts who published articles on Seeking Alpha such as John Engle, Synergy investors were shocked by the news of the share offering because approximately two-months earlier the Company had announced that the *non-dilutive* CRG Loan would fund the commercialization of Trulance through 2019 and was available to Synergy "if and when" needed: "This was shocking news to shareholders, myself included, who thought a recently arranged \$300 million debt facility removed any short or near term funding needs for the company." Nov. 15, 2017 Bret Jensen Article, Seeking Alpha, *Synergy Pharmaceuticals: How to Destroy Shareholder Value*.<sup>43</sup>

#### **M. Synergy Files For Bankruptcy After The Class Period**

111. On December 12, 2018, Synergy filed for bankruptcy. *See In re: Synergy Pharmaceuticals Inc., et al.*, No. 1:18-bk-14010 (Bankr. S.D.N.Y. Dec. 12, 2018) ("Bankruptcy Action"). As part of its filing, Gemignani explained that Synergy ultimately defaulted on the CRG Loan, and initiated Chapter 11 bankruptcy proceedings to facilitate Synergy's sale to Bausch Health Companies. Bankruptcy Action, ECF No. 16, Gemignani Decl. ¶¶23, 43-48.

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<sup>43</sup> <https://seekingalpha.com/article/4125292-synergy-pharmaceuticals-destroy-shareholder-value>.

112. Trulance’s non-superiority also played a role in Synergy’s bankruptcy. Indeed, as one analyst at Bloomberg stated regarding Synergy’s bankruptcy, “[B]iotech firms should exercise more caution in pursuing me-too drugs, and investors should be wary of overvaluing such medicines before they prove able to gain profitable market share.” Dec. 12, 2018 Max Nisen Article, Bloomberg Opinion, WashingtonPost.com, *No Emoji Could Hide This Drugmaker’s Woes*, [https://www.washingtonpost.com/business/no-emoji-could-hide-this-drugmakerswoes/2018/12/12/c73699b4-fe43-11e8-a17e-162b712e8fc2\\_story.html](https://www.washingtonpost.com/business/no-emoji-could-hide-this-drugmakerswoes/2018/12/12/c73699b4-fe43-11e8-a17e-162b712e8fc2_story.html).

## V. ADDITIONAL SCIENTER ALLEGATIONS

113. As alleged herein, Defendants acted with scienter because at the time they made their public statements, they knew or recklessly disregarded the fact that such statements were materially false and misleading and/or omitted material facts concerning their claims of Trulance’s superiority and the dilutive nature of the CRG Loan, its availability “if and when” needed, its sufficiency in funding the commercialization of Trulance through 2019, and the Cash Condition Precedent. Defendants knew that such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and/or recklessly participated in the issuance and/or dissemination of such statements and/or documents nonetheless.

### A. *Respondeat Superior* and Agency Principles Apply

114. Synergy is liable for the acts of Defendants and other Company officers, directors, employees, and agents under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of Defendants and other Company officers, directors, employees, and agents is similarly imputed to Synergy under *respondeat superior* and agency principles.

**B. Defendants' And Synergy's Conscious Misbehavior Regarding Their Claims of Trulance's Superiority**

115. All Defendants and Synergy had possession of or access to information showing that their claims of Trulance's superiority with respect to its side-effects were false and/or misleading and omitted material information.

116. Defendants were aware of and/or had access to the evidentiary requirements imposed by the FDA for drug superiority claims. For example, Synergy's Annual Report on Form 10-K for the year 2016, which was signed by Defendants Jacob and Gemignani, states Synergy's "product candidates are regulated by the FDA as drugs" and that "[t]he conduct of the [Phase 3] clinical trials is subject to extensive regulation, including compliance with good clinical practice regulations and guidance." 2016 Annual Report at 9-10. And, when asked whether Trulance was more *effective*—as opposed to safer—than its competition, Defendant Garcia stated, "*We don't have any head-to-head studies versus other competitors*, but clearly with this as you—as you saw the efficacy is very robust, a nice clear speculation [sic]. . . . But again, *without head-to-head studies*, all I can say is the efficacy we think is going to be a bit of an advantage being able to speak to the durable endpoints." Synergy at Jefferies 2016 London Healthcare Conference on Nov. 16, 2016, Wall Street Webcasting Transcript at 10.

117. Defendants were also aware of the FDA's requirements for promotional material. For example, Synergy's Form 10-K for the year 2016, which was signed by Defendants Jacob and Gemignani, acknowledges that Synergy must "comply with FDA promotion and advertising requirements and restrictions." 2016 Annual Report at 11. Similarly, Synergy, through its Vice President of Regulatory Affairs & Clinical Quality Assurance, Evelyn Jaeger, was aware of the FDA's requirements on advertising and promotional materials, as evidenced by the filings of dozens of Form 2253s with the FDA signed by Jaeger. *See, e.g.*, Exs. E, F.

118. Additionally, several Defendants were aware of and/or had access to Trulance's and Linzess' clinical data, including the fact that Trulance's Phase 3 trial recorded incidents of diarrhea differently than Linzess' trials, as evidenced by their discussions of these two drugs' trials. For example, during the March 21, 2017 conference call, Defendant Garcia discussed the diarrhea rates seen in Trulance's clinical trials and other trial data. *See* Synergy Pharmaceuticals Inc. at Oppenheimer Healthcare Conference on Mar. 21, 2017, Fair Disclosure Wire Transcript at 3. Defendant Jacob signed the 2016 Annual Report, which also discussed Trulance's Phase 3 trials, including the trial's diarrhea rates. 2016 Annual Report at 5, 57. During a conference call with investors on August 16, 2012, Jacob compared the *design* of the then-upcoming Trulance Phase 3 trials to Linzess' phase 3 trials, stating, “[t]he trial is designed much the way the *linaclotide trial was conducted*[.]” Synergy at Canaccord Genuity's Global Growth Conference on Aug. 16, 2012, at Fair Disclosure Wire Transcript 5.

119. Defendants were made further aware of the false and misleading nature of their statements when Ironwood objected to statements made by Synergy and its officers to investors. As far back as August 16, 2012, Defendant Jacob described competitor Linzess as derived from an “enterotoxin . . . used by a bacterium that provides traveler's diarrhea; whereas [Trulance] is actually a direct analog of uroganylin itself.” Synergy at Canaccord Genuity's Global Growth Conference on Aug. 16, 2012, Fair Disclosure Wire Transcript at 3. Ironwood—Linzess' co-marketer—objected to Synergy and Defendants' explicit mischaracterizations of Linzess. *See* ECF No. 39-1(Allergan letter, Challenge to Synergy Pharmaceuticals Advertising)<sup>44</sup> at 26.

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<sup>44</sup> This letter was previously filed in this Action at ECF No. 39-1, Exhibit A, Part 1, to the Declaration of Richard W. Gonnello In Support Of Robert Tilton and Cross Country Media and Sourcing, Inc.'s Request for Judicial Notice of Documents In Further Support Of Their Lead Plaintiff Motion.

However, Defendants continued to misrepresent that Trulance was superior to Linzess (and Amitiza), prompting Allergan (Ironwood's partner) on September 1, 2017 to seek resolution with the National Advertising Division of the Better Business Bureau ("NAD"), which is an industry system of self-regulation. *See id.* at 12-30.

120. Defendants' knowledge of the groundlessness of their superiority claims, including the FDA's requirement for head-to-head trials, is further evidenced by Jacob's response to Allergan's letter to the NAD. In a letter dated September 6, 2017 and addressed to Jacob, the NAD inquired with Synergy about its false and misleading advertising and asked Synergy to "provide substantiation for [its] claims" including "all relevant product testing, market data, and any consumer research[.]" Ex. G at 2 (NAD's Sept. 6, 2017 Letter To Jacob regarding "Advertising for Trulance™"). Instead of presenting any evidence to support its claims, Jacob acknowledged familiarity with FDA rules, regulations, and guidance, but nevertheless declined to produce any information that would demonstrate compliance. ECF No. 39-2<sup>45</sup> at 18-19 (Jacob responds to NAD by declining to participate and offers no evidence to substantiate any of Synergy's superiority claims). Jacob's and Synergy's *failure to offer any evidence* in the face of the NAD's and Allergan's claims supports an inference of scienter because any reasonable company confronted by such claims would have responded with evidence if they were not true. Jacob's response also provides further support for the inference that he is aware of "FDA rules, regulations, and guidance."

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<sup>45</sup> Jacob's response was previously filed in this Action at ECF No. 39-2, Exhibit A, Part 2, to the Declaration of Richard W. Gonnello In Support Of Robert Tilton and Cross Country Media and Sourcing, Inc.'s Request for Judicial Notice of Documents In Further Support Of Their Lead Plaintiff Motion.

121. Moreover, Defendants encouraged investors and analysts to view Synergy’s promotional materials. For example, when asked by an analyst how Synergy would convince doctors to prescribe Trulance over Linzess, Defendant Jacob highlighted Synergy’s promotional materials to investors, stating, “*And you probably see that in some of the other materials that we have in our campaign right now[.]*” Synergy at Deutsche Bank Healthcare Conference on May 3, 2017, Fair Disclosure Wire Transcript at 7. Jacob also stated, “*We* have a lot going on here. There is point-of-care promotions, *so that would be in-office print or displays.*” *Id.* at 6. In another conference call on March 21, 2017, Defendant Garcia told analysts that Synergy had “*promotion through digital media and social media campaigns[] [a]nd you can see some of the materials that have been produced.*” Synergy at Oppenheimer Healthcare Conference on Mar. 21, 2017, Fair Disclosure Wire Transcript at 4. Garcia also directed investors to Synergy’s website during the same call, stating “*I am very excited to share this—and you can go to our website and see more of it, but it is incredibly powerful creative campaign based on a lot of marketing insights from a lot of marketing research, and we are really pleased.*” *Id.* at 3. In a conference call on May 3, 2017, Hamilton also touted Synergy’s Trulance “website” for patients and doctors, “branded” and “unbranded” advertising campaigns, and other marketing mediums to investors, including “in-office print” ads. Synergy at Deutsche Bank Health Care Conference on May 3, 2017, Fair Disclosure Wire Transcript at 6.

122. Lastly, Defendants conducted an on-going review of these promotion materials, as Jacob admitted that Synergy’s advertising and promotional materials were part of “*our* on-going review.” ECF No. 39-2 at 18.

### C. Defendants’ Conscious Misbehavior Regarding The CRG Loan

123. All Defendants had possession of or access to information showing that their statements regarding the CRG Loan were false and/or misleading.

124. Defendant Gemignani signed the CRG Loan on Synergy's behalf, which was dated September 1, 2017. *See* Term Loan Agreement, at 1, 70 (Ex. 10.2 to Form 10-Q) (Nov. 9, 2017). Further, the Loan required that a resolution of the Synergy Board, of which Defendant Jacob was a member. *Id.* § 6.01(g)(v). Since the first tranche of \$100 million borrowing pursuant to the Loan was extended to Synergy, the entire Board, including Defendant Jacob, had to have not only been informed of the Loan and its terms, but approved them by official resolution. Further, it is represented in the CRG Loan that the entry into the Loan was "duly authorized by all necessary corporate or equivalent action." *Id.* at § 7.02. Therefore, Gemignani and Jacob knew about the full terms of the CRG Loan, which necessarily included the Cash Condition Precedent, when they discussed the Loan. In any event, Jacob, Gemignani, and Hamilton acted either knowingly or recklessly when they discussed the CRG Loan because they had access to the entire CRG Loan agreement before they began making false/misleading statements and omissions regarding the CRG Loan on September 5, 2017. *See* Term Loan Agreement.

125. Gemignani also chose to discuss certain terms of the CRG Loan, but not others, demonstrating that he possessed actual knowledge of the terms of the Loan, but chose to conceal the Cash Condition Precedent and its import. For example, in a press release announcing the CRG Loan, defendant Gemignani claimed that it was "[t]he structure" of the loan which provided Synergy financial flexibility. Sept. 5, 2017 Synergy Press Release, *Synergy Pharmaceuticals Secures \$300 Million Debt Financing*. Gemignani also touted the "structure" of the CRG Loan as non-dilutive again during a conference call with analysts on September 7, 2017. Q2 2017 Synergy Pharmaceuticals Inc. Earnings Call on Sept. 7, 2017, Bloomberg Transcript at 3. Gemignani also claimed that he "looked at numerous types of structures" when

determining how to structure the CRG Loan and that he and Synergy performed “extreme amounts of diligence” with respect to the CRG Loan. *Id.* at 8. Having claimed such intimate knowledge of the CRG Loan, Gemignani cannot now feign ignorance of its most material terms, including the \$128 million Cash Condition Precedent that was necessary to unlock \$100 million in financing.

126. Further demonstrating Gemignani’s knowledge of the structure of the CRG Loan is that months before entering into the Loan, he was advised by an experienced investment bank, Cantor Fitzgerald, retained by Synergy to advise on securing financing to commercialize Trulance, and how to structure debt transactions. *See* Complaint at ¶¶14-29, *Cantor Fitzgerald & Co. v. Synergy Pharmaceuticals Inc., et al.*, Index No. 657033/2017 (N.Y. Sup. Ct. Nov. 20, 2017). The CRG Loan was “structured identically to the transaction Cantor had recommended for Synergy in April 2017.” *Id.* ¶43.

127. Also demonstrating Defendants’ knowledge or reckless disregard of the structure of the CRG Loan is that the 8-K (signed by Defendant Jacob and filed with the SEC on September 5, 2017) disclosing entry into the Loan discusses various covenants and requirements contained in the Loan, but omits mention of the Cash Condition Precedent. ¶91.

128. Defendants were also aware at the time Synergy entered into, and soon after announced entry into, the CRG Loan, that: (i) Synergy’s \$117.8 million cash position was below the requirements of the Cash Condition Precedent; (ii) Synergy’s \$61.3 million cash burn rate vastly exceeded its revenues; (iii) Synergy’s go-it-alone commercialization strategy for Trulance required the Company to incur substantial amounts of SG&A and other expenses going forward; and (iv) the \$128 million Cash Condition Precedent all but necessitated a dilutive equity offering, as evidenced by, *inter alia*, the fact that Synergy’s quarterly reports disclosing the

Company's cash position and cash burn were accompanied by Rule 13a-14(a)/15d-14(a) certifications under the Exchange Act, signed by Jacob and Gemignani, which attested, *inter alia*, that they “***reviewed th[e] [forms] 10-Q[,]” and designed disclosure controls and procedures to “ensure that material information . . . is made known”*** to them. *See* Ex. 31.1 to Synergy Form 10-Q, filed with the SEC on May 10, 2017; Ex. 31.2 to Synergy Form 10-Q, filed with the SEC on May 10, 2017; Ex. 31.1 to Synergy Form 10-Q, filed with the SEC on Aug. 9, 2017; Ex. 31.2 to Synergy Form 10-Q, filed with the SEC on Aug. 9, 2017; Ex. 31.1 to Synergy Form 10-Q, filed with the SEC on Nov. 9, 2017; Ex. 31.2 to Synergy Form 10-Q, filed with the SEC on Nov. 9, 2017.

129. Furthermore, Defendants Jacob, Gemignani, and Hamilton were aware of and/or had access to the facts of Synergy's \$61.3 million cash burn rate and \$2.5 million average Trulance revenues, as evidenced by the fact that they understood that Synergy was not cash flow positive and would not be cash flow breakeven until 2019. *See* Synergy Q2 2017 Business Update Call on Sept. 7, 2017, Bloomberg Transcript at 2-3. During a conference call with investors on September 7, 2017 conducted by Defendants Jacob, Gemignani, and Hamilton, Defendant Gemignani claimed that the Company expected to be “cash flow breakeven” in 2019. *Id.* at 3. Defendant Gemignani was also aware of Synergy's cash burn rate when he announced the Loan, as evidenced by his statement on September 7, 2017 that the cash burn rate going into “the second half of 2017” was “in line with the first half of [2017].” *Id.* at 3. These statements evidence intricate knowledge of Synergy's financial condition, and, in particular, its revenues and cash burn rate. Without such intricate knowledge, Defendants' publicly issued guidance for Synergy to be cash-flow breakeven by 2019 would have no basis in fact and would be fraudulent

in and of itself. Rather, it is indisputable that Defendants carefully tracked Synergy's cash burn rates and factored that knowledge into their public guidance for Synergy's fiscal 2019.

130. Synergy and Defendants also had access to information concerning Trulance revenues through QuintilesIMS. QuintilesIMS is a "healthcare information" provider which provides its clients with "comprehensive, longitudinal, anonymous patient records" including "*sales, prescription and promotional data.*" QuintilesIMS, Form 10-K at 5, filed on Feb. 16, 2017. During the Class Period, Synergy tracked weekly and monthly Trulance prescriptions through QuintilesIMS. For example, during a May 3, 2017 conference call, Hamilton presented detailed prescription data "from QuintilesIMS[.]" including monthly and weekly data. Synergy at Deutsche Bank Healthcare Conference on May 3, 2017, Fair Disclosure Wire Transcript at 4 (.).

#### **D. Defendants' Pharmaceutical And Financial Experience**

131. Defendants were highly educated, trained, and experienced in drug development, marketing, and/or financing and were therefore well-aware that their statements regarding Trulance's purported superiority and the CRG Loan were false and/or misleading and omitted material information.

132. As set forth below, Defendants are sophisticated pharmaceutical executives who are well-versed in the customs and practices of their industry. Therefore, they were aware of the FDA's requirement for an adequate and well-controlled head-to-head clinical trial for superiority claims, or if they were not aware, knew that the investing public expected that they kept themselves apprised of the FDA's requirements.

133. Defendant, CEO and Chairman Jacob has over twenty-five years of experience in the pharmaceutical and biotechnological industry. Synergy, Proxy Statement (on Form 14A), at 10, filed with the SEC on Apr. 17, 2017. Jacob holds a Ph.D. in Biochemistry from the University of Wisconsin-Madison and a BS in Biochemistry from the same school.

Bloomberg.com, *Executive Profile: Gary S. Jacob*.<sup>46</sup> Significantly, Jacob is the co-inventor of Trulance, and is therefore aware of Trulance's uses and side-effects. *See* Nov. 16, 2016 Synergy Presentation, Slides For Jefferies London Healthcare Conference, at 3.

134. Defendant and CFO Gemignani's career in healthcare spans over three decades. Synergy Proxy Statement (on Form 14A), at 29, filed with the SEC on Apr. 20, 2018. Before joining Synergy in April 2017, Gemignani served as CEO and CFO of Biodel, Inc. *Id.* Additionally, Gemignani has served in executive financial and operational roles with multiple companies, including Novartis. Gemignani holds a BS from St. Peter's College. *Id.* When Gemignani was appointed, Synergy praised his "extensive expertise in financial and operational management[.]" Apr. 17, 2017 Synergy Press Release, *Synergy Pharmaceuticals Appoints Gary G. Gemignani As Chief Financial Officer*.

135. Defendant and CSO Garcia possesses over 20 years of experience in commercial, new product planning, and business development roles. Synergy Proxy Statement (on Form 14A), at 29, filed with the SEC on Apr. 20, 2018. Garcia received a Bachelor's Degree in Business Administration from Concordia University in Montreal, Quebec, and an M.B.A. from the Richard Ivey School of Business at Western University in London, Ontario. *Id.* at 30. Among the roles he served in, Garcia was Vice President of Global Business Development at Aptalis Pharma, which was a specialty company focused on the gastrointestinal market—the same market Synergy is focused on. Mar. 10, 2016 Synergy Press Release, *Synergy Pharmaceuticals Appoints Marino Garcia As Chief Strategy Officer*.

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<sup>46</sup> <https://www.bloomberg.com/research/stocks/people/person.asp?personId=8717405&privcapId=731580>.

136. Defendant and CCO Hamilton has over 20 years of experience in the pharmaceutical industry, including 9 years at Shire Pharmaceuticals, Inc. and 10 years at Johnson & Johnson's Janssen Pharmaceuticals. Synergy Proxy Statement (on Form 14A), at 36, filed with the SEC on Apr. 17, 2017. Hamilton holds a BS in Pharmacy and a PharmD (Doctor of Pharmacy) from the University of the Sciences in Philadelphia and an MBA from St. Joseph's University. *Id.*

**E. Defendants' Financial Motive**

137. Defendants were motivated to artificially inflate Synergy's stock price because doing so allowed Synergy to obtain more cash via frequent public and private share offerings entered into prior to the CRG Loan:

- On November 10, 2016, Synergy privately exchanged 12,911,914 shares of the Company's stock for an aggregate principal amount of \$35 million in 7.50% Convertible Senior Notes due 2019 held by OrbiMed Advisors LLC and OrbiMed Capital LLC. *See* Synergy Form 8-K at 2, filed with the SEC on Nov. 15, 2016.
- On November 16, 2016 and November 21, 2016, Synergy entered into separate privately negotiated exchange agreements, exchanging 7,555,683 shares of the Company's stock for an aggregate principal amount of \$20.7 million of the Company's 7.50% Convertible Senior Notes due 2019. *See* Synergy Form 8-K at 2, filed with the SEC on Nov. 21, 2016.
- On or around February 6, 2017, Synergy closed a public offering of 20,325,204 shares at \$6.15 per share, raising approximately \$125 million. *See* Feb. 1, 2017

Synergy Press Release, *Synergy Pharmaceuticals Announces Pricing Of Public Offering Of Common Stock*.<sup>47</sup>

138. Defendants' materially false and/or misleading statements artificially inflated the price of Synergy's shares, and as a result, the Company was able to raise \$125 million from investors, and erase an additional \$55.7 million in principal owed to noteholders. In total, Synergy obtained over \$180 million in value from the issuance of artificially inflated shares.

139. Defendants were further motivated to artificially inflate Synergy's stock so that they could use the funds obtained to commercialize Trulance. *See* Synergy Prospectus Supplement (on Form 424B5), at S-5, filed with the SEC on Feb. 2, 2017 ("We intend to use the net proceeds from this offering to fund our commercialization activities related to TRULANCE, further research and development of plecanatide and for working capital and other general corporate purposes."); Nov. 13, 2017 Synergy Press Release, *Synergy Pharmaceuticals Announces Pricing of Offering of Common Stock and Warrants* (same).

140. Defendants were also motivated to artificially inflate Synergy's stock price in conjunction with these offerings to stave off bankruptcy, as acknowledged by Synergy's independent registered public accounting firm in a report "expressing substantial doubt in the Company's ability to continue as a going concern without additional capital becoming available." *See* 2016 Form 10-K at 15; Synergy Form 10-Q at 8, filed with the SEC on Aug. 9, 2017. Synergy's dilutive share offering bought the Company at least another year, as eventually, Synergy filed for bankruptcy on December 12, 2018, in part because it was in default of the CRG Loan's terms. *See* Current Report on Form 8-K filed with the SEC on December 13, 2018.

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<sup>47</sup> <https://ir.synergypharma.com/press-releases/detail/1833/synergy-pharmaceuticals-announces-pricing-of-public>

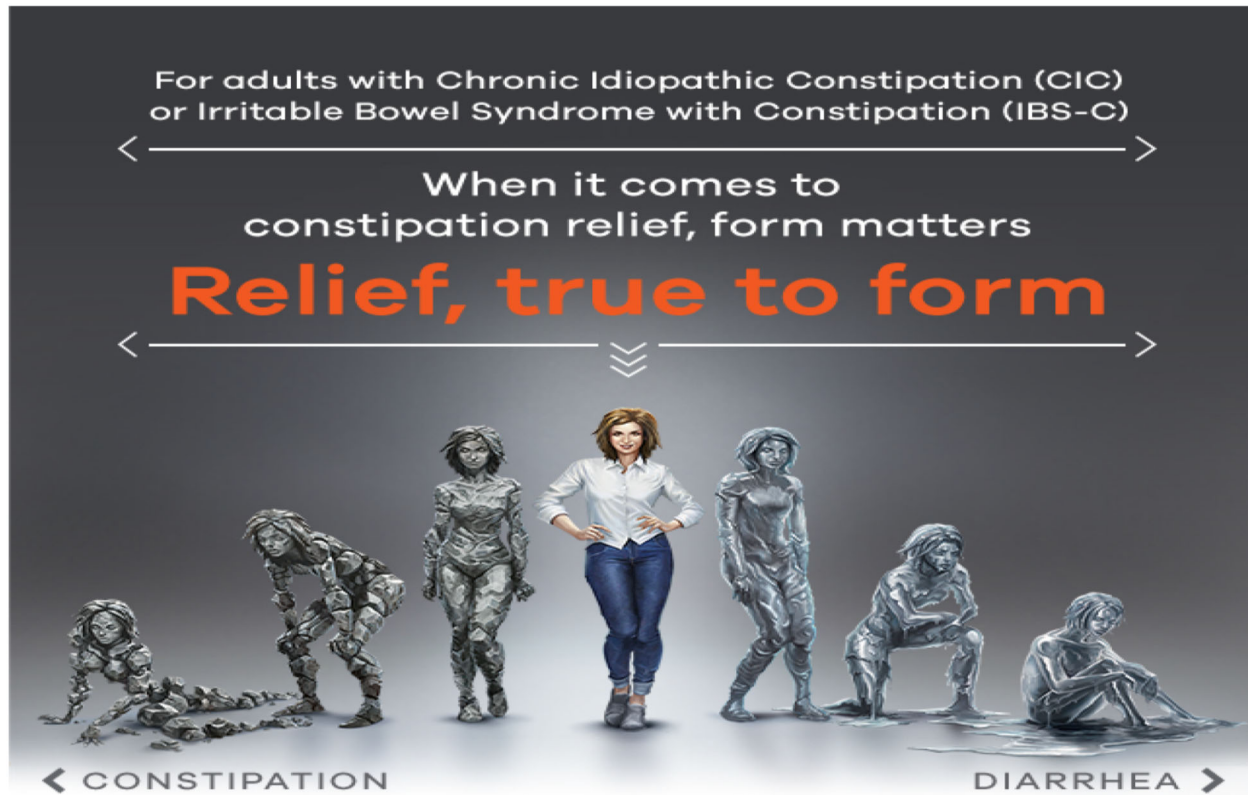
**F. Defendants' Concealment Of Synergy's Misleading Promotional Materials**

141. Defendants failed to file the Guide To CIC with the FDA, as required by FDA regulations. Under 21 C.F.R. § 314.81(b)(3)(i), drug companies must “*submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product.*” However, while Synergy filed Form 2253s for several advertisements and Trulance promotional materials, the FDA does not possess a Form 2253 filed by Synergy containing the Guide To CIC,<sup>48</sup> which was clearly devised to promote Trulance. The FDA appears to only possess a Form 2253 filed on February 17, 2017 for the Trulance advertisement and depiction in ¶52, *supra*, but not the Guide To CIC. Compare Ex. H (Form 2253 for Health Monitor advertisement), with Ex. B (full Guide To CIC). Synergy's failure to file the Guide To CIC was not inadvertent given the blatant misrepresentations within, and is further evidence of Defendants' conscious misbehavior.

142. Additionally, some time after the Class Period, Synergy removed false and misleading content from its website. Specifically, as depicted the below, Synergy's websites for Trulance.com and Trulancehcp.com no longer contained the false and misleading statements cited in ¶¶56, 59, *supra*. Compare ¶¶56, 59, and Exs. E, F, with, Trulance.com, and Trulancehcp.com.

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<sup>48</sup> This is based on the FDA's FOIA litigation production of Forms 2253 and advertising or marketing materials provided to the FDA by Synergy.



For adults with Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C)

**Efficacy, true to form**

For your patients with CIC or IBS-C, closer to the middle is where they want to be.<sup>1,2</sup>

Trulance provided more regular, well-formed bowel movements and less IBS-C related abdominal pain.<sup>3\*</sup>

Trulance is the only structural analog of human uroguanylin and is believed to replicate the pH-sensitive activity of uroguanylin.<sup>3,4†</sup>

Learn more about the mechanism of action >

Discover the clinical results for Trulance >

Find out about user-friendly dosing >

The advertisement features a central figure of a woman in a white shirt and blue jeans, standing with hands on hips. To her left, a series of figures in a metallic, segmented suit transition from a crouched, struggling position to a standing position. To her right, a similar series of figures transitions from a standing position to a crouched, struggling position. The background is dark grey with white and orange text.

\*Results over 12 weeks were statistically significant vs placebo in four Phase 3 clinical studies.<sup>3</sup>

## G. Defendants' Concealment Of The Cash Condition Precedent

143. Defendants initially concealed the Cash Condition Precedent from investors by omitting its existence in the Form 8-K they filed with the SEC on September 5, 2017 and by

omitting its existence in the press release disclosing the CRG Loan that was publicly disseminated and attached as an exhibit to the Form 8-K. Defendants also initially concealed the Cash Condition Precedent by failing to file the CRG Loan with the Form 8-K they filed on September 5, 2017 and by failing to provide the material terms of the CRG Loan in the press release disseminated on September 5, 2017, and attached to the Form 8-K, first announcing the Loan. *See* Synergy Form 8-K, filed with the SEC on Sept. 5, 2017.

144. On November 9, 2017, during a conference call with investors which started at 4:30 p.m., Defendant Gemignani continued to falsely describe the CRG Loan as “*non-dilutive[.]*” Synergy Q3 2017 Earnings Call on Nov. 9, 2017, Bloomberg Transcript at 5. Gemignani—the same Synergy executive who signed the CRG Loan—concealed the existence of the Cash Condition Precedent and its impact on the value of Synergy stock, stating:

*While I cannot comment on specific conditions required to access the additional tranches beyond what’s publicly disclosed*, I can tell you that we are confident in our ability to meet the conditions that will allow us to access to the additional capital if and when we need it.

*Id.* Gemignani’s obfuscation bought Synergy time to dilute its shareholders via a \$56 million public offering, diluting shareholder interests by about 10%, announced approximately two trading days later. Nov. 13, 2017 Synergy Press Release, *Synergy Pharmaceuticals Announces Pricing of Offering of Common Stock and Warrants*.

## H. SOX Certifications

145. Defendants Jacob and Gemignani signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) that they filed with the SEC in connection with the filing of Synergy’s May 10, 2017, August 9, 2017, and November 9, 2017 Forms 10-Q quarterly reports for the quarters ended March 30, 2017, June 30, 2017, and September 30, 2017. For each of those quarterly reports, Jacob and Gemignani certified that the quarterly report “Form 10-Q fully

complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.” *See* Ex. 32.1 to Synergy Form 10-Q, filed with the SEC on May 10, 2017; Ex. 32.2 to Synergy Form 10-Q, filed with the SEC on May 10, 2017; Ex. 32.1 to Synergy Form 10-Q, filed with the SEC on Aug. 9, 2017; Ex. 32.2 to Synergy Form 10-Q, filed with the SEC on Aug. 9, 2017; Ex. 32.1 to Synergy Form 10-Q, filed with the SEC on Nov. 9, 2017; Ex. 32.2 to Synergy Form 10-Q, filed with the SEC on Nov. 9, 2017.

146. The SOX certifications add to the inference that their signatories, Jacob and Gemignani, acted with scienter. Specifically, the SOX certifications are evidence that Jacob and Gemignani were fully aware of Synergy’s “financial condition,” including the Company’s cash position, cash-burn rate, and Trulance revenues, as disclosed in Synergy’s Form 10-Qs for the first three quarters of 2017, along with the entire CRG Loan’s terms, including the Cash Condition Precedent, which Synergy filed with the SEC in its November 9, 2017 Form 10-Q.

### **I. Terminations And Resignations**

147. The timing of Defendant Jacob’s December 13, 2017 resignation suggests he was aware of and/or had access to information showing that claims regarding Trulance’s purported superiority and statements regarding the CRG Loan were false and/or misleading and omitted material information. According to the Current Report on Form 8-K and attached press release filed with the SEC, Hamilton would replace Jacob as CEO, “effective immediately.” Ex. 99.1 to Synergy Form 8-K, filed with the SEC on Dec. 19, 2017. The Form 8-K also reveals that Synergy had appointed Hamilton to the CEO position six days earlier, on December 13, 2017—exactly one month after the November 13, 2017 announcement of Synergy’s dilutive public offering and a little more than a month after the Company revealed the third quarter slowdown in

Trulance's prescription growth rate. Synergy Form 8-K, filed with the SEC on Dec. 19, 2017.

The suspicious timing of Jacob's sudden resignation suggests that the resignation was linked to the fraud alleged herein.

#### **J. Importance Of Trulance To The Company**

148. Because the fraud alleged herein relates to the primary business of Synergy, knowledge of the facts underlying the fraud may be imputed to Defendants. Indeed, during the Class Period, Trulance was the Company's sole commercialized drug. *See* 2016 Annual Report at 3. As such, Synergy admitted in its SEC filings that it was "largely dependent on the commercial success of Trulance in the U.S. for the foreseeable future." 2016 Annual Report at 13. Therefore, Defendants, as senior executives, were in such positions at the Company to access all material, non-public information concerning Trulance, including, *inter alia*, Trulance's clinical trials, Trulance's promotional materials, and the FDA regulations requiring adequate and well-controlled head-to-head trials for their superiority claims, and undoubtedly did so given their fiduciary duties. Further, Defendants, as senior executives, were in such positions at the Company to access all material, non-public information concerning the CRG Loan, which was extended to fund the commercialization of the Company's only commercialized drug, Trulance.

149. Moreover, Synergy's promotional campaign for Trulance was central to its strategy. For example, at the Canaccord Genuity Growth Conference on August 11, 2016 attended by Garcia, Synergy presented slides indicating that one of its "***major initiatives***" ***was to raise "awareness of Synergy Pharmaceuticals and the unmet needs/burden" of CIC patients.*** Aug. 11, 2016 Synergy Presentation, *Canaccord Genuity Growth Conference*, at 22. As later demonstrated by Synergy's BURDEN-CIC survey, the burden and unmet needs Synergy and Garcia alluded to was alleviating CIC in patients without causing diarrhea side effects. May 7, 2017 Synergy Press Release, *Synergy Presents New Insights at Digestive Disease Week (DDW)*

*Examining Patients and Physician Perceptions and Experiences with Chronic Idiopathic Constipation (CIC)* ; Lucinda A. Harris, et al., *The Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients with Chronic Idiopathic Constipation (BURDEN-CIC) Study: Results of an Online Questionnaire* (Adv. Ther. 2017) (“The BURDEN-CIC study emphasizes the unmet needs of CIC patients as well as those of the HCPs who treat these patients.”).<sup>49</sup> Further, the CRG Loan was integral to Synergy’s strategy for the commercialization of Trulance, purportedly providing the financing needed to fund such commercialization efforts through 2019.

150. In any event, given the importance of Trulance and the CRG Loan to the launch and commercialization of Trulance, it is reasonable to infer from the detailed allegations herein that Defendants were aware of the facts that were omitted and misrepresented by them as alleged herein.

## **VI. LOSS CAUSATION**

151. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused Lead Plaintiffs and the Class to suffer substantial damages.

152. During the Class Period, Lead Plaintiffs and other Class members purchased Synergy securities at artificially inflated prices, and suffered substantial losses and damages when the true facts concealed by the Defendants’ fraud were revealed and/or when the risks concealed by those undisclosed facts materialized. The price of Synergy securities declined significantly causing Lead Plaintiffs and other Class members to suffer losses and damages when the Defendants’ misrepresentations, and/or information alleged herein to have been concealed

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<sup>49</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5709448/>.

from the market, and/or the effects thereof, were revealed, and/or the foreseeable risks that had been fraudulently concealed by the Defendants materialized.

153. Defendants made false and misleading statements and material omissions regarding the purported superiority of Trulance's diarrhea side-effect profile (§§48-49, 52-64), and the CRG Loan (§§89-92, 95-96, 100-01). On the strength of these false and misleading statements and material omissions, the Company's stock price was artificially inflated to a Class Period high of \$7.15 per share on January 31, 2017. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Synergy's business, operations, performance, and prospects. When these statements were corrected and/or the risks concealed by them materialized, investors suffered losses as the price of Synergy common stock declined.

154. The true facts and risks regarding Synergy's lack of evidence for Trulance's purported superiority to its competitors with respect to the diarrhea side-effect which were omitted and/or misrepresented by the Defendants eventually caused the price of Synergy stock to decline on three occasions, thereby causing harm to investors.

155. First, Defendants' and Synergy's statements were partially corrected, and the risks concealed by the undisclosed facts regarding Trulance's purported superiority materialized when, on July 31, 2017, Express Scripts published its 2018 National Preferred Formulary, which excluded Trulance but included Linzess and Amitiza as preferred alternatives, causing investors to suffer losses as Synergy's share price fell \$0.18 per share, or approximately 4.4% from the previous trading day's closing price of \$4.06, to close at \$3.88 on July 31, 2017. *See* §§65-71.

156. Then, Defendants' and Synergy's statements were further partially corrected, and the risks concealed by the undisclosed facts regarding Trulance's purported superiority further materialized when, on August 9, 2017, the Company's 2Q 2017 Presentation revealed that weekly growth rate in Trulance prescriptions had nearly flat-lined at 4.46% for the month of July, causing investors to suffer losses as Synergy's share price fell \$0.46 per share, or approximately 13.03% from the previous trading day's closing price of \$3.53, to close at \$3.07 on August 10, 2017. *See* ¶¶74-75.

157. Then, Defendants' and Synergy's statements were further corrected, and the risks concealed by the undisclosed facts regarding Trulance's purported superiority further materialized when, on November 9, 2017, the Company's 3Q 2017 Presentation revealed that growth in Trulance prescriptions had nearly flat-lined and that individual prescribers were writing fewer Trulance prescriptions, causing investors to suffer losses as Synergy's share price fell \$0.25 per share, or approximately 8.42% from the previous trading day's closing price of \$2.97, to close at \$2.72 on November 10, 2017. *See* ¶¶102-03.

158. The true facts and risks regarding the CRG Loan and the Cash Condition Precedent caused the price of Synergy stock to decline on two occasions, thereby causing harm to investors.

159. Defendants' statements were partially corrected, and the risks concealed by the undisclosed facts concerning the CRG Loan materialized when, on November 13, 2017 pre-market open, Synergy announced the pricing of a \$56 million share offering, causing investors to suffer losses as Synergy's share price fell \$0.28 per share, or approximately 10.3% from the previous trading day's closing price of \$2.72, to close at \$2.44 per share on November 13, 2017. *See* ¶¶104-05.

160. Then, Defendants' statements were further corrected, and the risks concealed by the undisclosed facts concerning the CRG Loan materialized when, on November 14, 2017, Synergy revealed the existence of the Cash Condition Precedent, that the funds from the CRG Loan would not be available if and when needed, that the CRG Loan was not sufficient to fund the commercialization of Trulance through 2019, that Synergy could not draw upon the Loan when it chose to do so, and that it would be necessary to launch a dilutive equity offering to meet the Cash Condition Precedent's terms and access the remaining portions of the funding. Analysts and investors were shocked by the revelations of the truth regarding the CRG Loan and its Cash Condition Precedent. Indeed, BTIG issued a report lowering its price target for Synergy shares to \$7 from \$11, over 36%. Investors suffered heavy losses as Synergy's share price fell \$0.41 per share, or approximately 16.8% from the previous trading day's closing price of \$2.44, to close at \$2.03 per share on November 14, 2017. *See* ¶¶106-08.

161. Accordingly, as a result of their purchases of Synergy's publicly traded securities during the Class Period, Lead Plaintiffs and other members of the Class suffered economic losses and damages.

## **VII. CLASS ACTION ALLEGATIONS**

162. Lead Plaintiffs bring this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and all persons and entities who purchased Synergy securities listed on the NASDAQ or domestically in the United States at artificially inflated prices during the Class Period, and were damaged thereby, seeking to pursue remedies under the Exchange Act (the "Class").

163. Excluded from the Class are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with

any of the Defendants, and the legal representatives, heirs, successors-in-interest or assigns of such excluded persons.

164. Also excluded from the Class are those who purchased or otherwise acquired Synergy securities on foreign exchanges or purchased or otherwise acquired Synergy securities outside of the United States, in accordance with the United States Supreme Court's decision in *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 267 (2010) (“[I]t is in our view only transactions in securities listed on domestic exchanges, and domestic transactions in other securities, to which § 10(b) applies.”).

165. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Synergy common stock was actively traded on the NASDAQ, which is an efficient market. While the exact number of Class members cannot be determined at this early stage, Lead Plaintiffs believe that thousands of people held Synergy securities during the Class Period. Record owners and other members of the Class may be identified from records maintained by Synergy or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

166. Lead Plaintiffs' claims are typical of the claims of the Class because Lead Plaintiffs and all members of the Class were similarly affected by Defendants' unlawful conduct as complained herein.

167. Lead Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation. Lead Plaintiffs have no interests that are contrary to or in conflict with those of the Class.

168. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include, *inter alia*:

- a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;
- b) Whether Defendants' publicly disseminated statements made during the Class Period contained untrue statements of material fact and/or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- c) Whether and to what extent Defendants' material untrue statements and/or omissions of material fact caused the market price of Synergy's securities to be artificially inflated during the Class Period;
- d) Whether Defendants acted with the requisite level of scienter in omitting and/or misrepresenting material facts;
- e) Whether Defendants were controlling persons of Synergy;
- f) Whether reliance may be presumed pursuant to the fraud-on-the-market doctrine; and
- g) Whether Class members have sustained damages, and if so, the proper measure of damages.

169. Lead Plaintiffs know of no difficulty that will be encountered in the management of this action that would preclude its maintenance as a class action.

170. A class action is superior to all other available methods for the fair and efficient adjudication of this action because, among other things, joinder of all members of the Class is

impracticable. In addition, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it nearly impossible for members of the Class to bring individual actions.

#### **VIII. CONTROL PERSON LIABILITY**

171. Defendants, because of their positions with Synergy, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, advertisements, promotional materials, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each Defendant possessed the power to direct or cause the direction of the management and policies of Synergy. Each Defendant had a duty to promptly disseminate complete, accurate, and truthful information with respect to Trulance's side effect profile in comparison to other drugs and the CRG Loan. Each Defendant was provided with copies of the Company's SEC filings, reports, promotional materials, and press releases alleged herein to be false or misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each Defendant knew or recklessly disregarded that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading.

#### **IX. THE FRAUD ON THE MARKET PRESUMPTION**

172. The false and/or misleading statements alleged herein were material and public and, at all relevant times, the market for Synergy's securities was an efficient market for the following reasons, among others:

- a. Synergy's common stock was listed on the NASDAQ Stock Market, a highly efficient market;

- b. As a registered and regulated issuer of securities, Synergy filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;
- c. Synergy regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;
- d. The market reacted to public information disseminated by Synergy; and
- e. At least five analysts followed Synergy's business and wrote reports which were publicly available and affected the market place.<sup>50</sup>

173. As a result of the above, the market for Synergy's securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the securities' market prices. The historical daily trading prices and volumes of Synergy securities are incorporated herein by reference.

174. The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to overvalue Synergy's securities. Without knowledge of the misrepresented or omitted facts, Lead Plaintiffs and other members of the Class purchased Synergy securities between the time that the Defendants made the material misrepresentations and omissions and the time that the truth or concealed risk was revealed, during which time the price of Synergy's securities was artificially inflated by Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

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<sup>50</sup> See Yahoo! Finance, *Synergy Pharmaceuticals, Inc, Analysis*, <https://finance.yahoo.com/quote/SGYP/analysis?p=SGYP>.

**X. NO STATUTORY SAFE HARBOR**

175. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do not apply to any of the materially false and misleading statements and omissions alleged in this Complaint.

176. First, many of the identified false and misleading statements and omissions herein are not forward-looking statements, but instead are statements of current or historic fact, or are actionable in context because they omit then-existing material facts.

177. Second, many of the identified false and misleading statements herein were not identified as forward-looking statements.

178. Third, to the extent there were any forward-looking statements that were identified as such at the time made, those statements also contained statements of present or past facts and so are not entitled to protection under the safe harbor.

179. Fourth, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningfully cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements, such as, *inter alia*, that the Company's cash position would require a cash infusion via a public offering in order to meet the \$128 million Cash Condition Precedent or that the existence of the Cash Condition Precedent would prevent funds from the CRG Loan from being available to Synergy if and when needed or that the absence of evidence of Trulance's superiority with respect to the diarrhea side-effect may result in Trulance's exclusion from insurance and/or PBM formularies (such as Express Scripts) and impact Trulance sales. Such statements were also not accompanied by cautionary language that was meaningful because any such warnings or "risk" factors contained in, or incorporated by reference in, the relevant

press release, SEC filings, earnings call, or other public statements described herein were general, “boilerplate” statements of risk that would affect any pharmaceutical company, and misleadingly contained no factual disclosure of any of the specific details concerning the CRG Loan’s Cash Condition Precedent, Trulance, or similar important factors that would give investors adequate notice of such risks.

180. Fifth, to the extent there were any forward-looking statements, Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, or, by reason of what the speaker failed to note, was materially false and/or misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Synergy who actually knew that each such statement was false or misleading when made.

## **XI. CAUSES OF ACTION**

### **COUNT I**

#### **Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

181. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

182. This Count is brought under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against all Defendants.

183. During the Class Period, Defendants and Synergy violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder by making the false and misleading statements specified herein, including the statements in SEC filings, presentations, press releases, and conference calls concerning Trulance’s diarrhea side effect profile and the CRG Loan, whose truth they knowingly or recklessly disregarded when they failed to disclose material facts

necessary to make the statements made, in light of the circumstances under which they were made, not false or misleading.

184. The acts and scienter of Defendants and other Company employees are imputed to the Company under the principles of agency and *respondeat superior*.

185. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about Trulance's side effect profile and the CRG Loan, and the Company's operations and financial condition as reflected in the misrepresentations and omissions set forth above.

186. Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

187. As a result of Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Lead Plaintiffs and the Class were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

188. Lead Plaintiffs and other Class members purchased Synergy securities, without knowing that Defendants had misstated or omitted material facts about the Company's operations and financial performance or prospects. In doing so, Lead Plaintiffs and other Class members relied directly or indirectly on false and misleading statements made by Defendants,

and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements.

189. Lead Plaintiffs and other Class members were damaged as a result of their reliance on the Defendants' false and/or misleading statements and misrepresentations and omissions of material facts. Lead Plaintiffs and other Class members would not have purchased Synergy securities at the prevailing prices had they known the truth about the matters discussed above.

190. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other Class members have suffered damages in connection with their purchases or acquisitions of Synergy securities.

191. Lead Plaintiffs filed this action within two years after the discovery of the facts constituting the violation, including facts establishing scienter and other elements of Lead Plaintiffs' claims, and within five years after the violations with respect to Lead Plaintiffs' investments.

## **COUNT II**

### **For Violations of Section 20(a) of the Exchange Act Against All Defendants**

192. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

193. This Count is asserted against Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of all members of the Class.

194. As alleged herein, Defendants caused Synergy to violate Section 10(b) of the Exchange Act by knowingly and/or recklessly disseminating materially false and misleading statements and/or omissions throughout the Class Period.

195. Each Defendant, by reason of his status as a senior executive officer and/or director of Synergy, directly or indirectly, controlled the conduct of the Company's business and

its representations to Lead Plaintiffs and other Class members, within the meaning of Section 20(a) of the Exchange Act. Defendants directly or indirectly controlled the content of the Company's SEC filings, press releases, and other statements related to Lead Plaintiffs' and other Class members' investments in Synergy securities within the meaning of Section 20(a) of the Exchange Act. Therefore, Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

196. Defendants controlled and had the authority to control the content of the Company's SEC filings, press releases, promotional material, and other statements. Because of their close involvement in the every-day activities of the Company, and because of their wide-ranging supervisory authority, Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

197. Defendants knew or recklessly disregarded the fact that Synergy's representations were materially false and misleading and/or omitted material facts when made, and are therefore culpable participants in the fraud. In so doing, Defendants did not act in good faith. By virtue of their high-level positions and their participation in and awareness of Synergy's operations and public statements, Defendants were able to and did influence and control Synergy's decision making, including controlling the content and dissemination of the documents that Lead Plaintiffs and other Class members contend contained materially false and misleading information and on which Lead Plaintiffs and other Class members relied.

## **XII. PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiffs on their own behalf, and on behalf of the Class, demand judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiffs as Class representatives;
- B. Requiring Defendants to pay damages sustained by Lead Plaintiffs and the Class by reason of the acts and statements alleged herein;
- C. Awarding Lead Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorney's fees, expert and consultant fees, and other costs;
- D. Awarding damages in favor of Lead Plaintiffs and the other Class members where appropriate against all Defendants, jointly and severally, for all injuries sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law; and
- E. Awarding such other and further relief as this Court may deem just and proper.

### **XIII. JURY TRIAL DEMAND**

Lead Plaintiffs hereby demand a trial by jury on all triable claims.

Dated: November 30, 2020

Respectfully submitted,

By: /s/ Richard W. Gonnello  
Richard W. Gonnello

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